

EXHIBIT D

Scott Guelcher

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

| | |
|--------------------------------|--------------------|
| IN RE: ETHICON, INC., PELVIC |) |
| REPAIR SYSTEM PRODUCTS |) |
| LIABILITY LITIGATION |) |
| _____ |) |
| |) |
| THIS DOCUMENT RELATES TO THE |)Master File No. |
| FOLLOWING CASES IN WAVE 1 OF |)2:12-MD-02327 |
| MDL 200: |) MDL 2327 |
| |) |
| Marty Babcock v. Ethicon, Inc. |)JOSEPH R. GOODWIN |
| Civil Action No. 2:12-cv-01052 |)U.S. DISTRICT |
| |)JUDGE |
| [Complete caption below] |) |
| _____ | |

DEPOSITION OF

SCOTT GUELCHER

Taken on behalf of the Defendants

March 23, 2016

8:51 a.m.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Scott Guelcher

| Page 2 | Page 4 |
|--|---|
| <p>1 UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA 2 AT CHARLESTON 3 IN RE: ETHICON, INC., PELVIC) REPAIR SYSTEM PRODUCTS) 4 LIABILITY LITIGATION) 5) 6 THIS DOCUMENT RELATES TO THE)Master File No. FOLLOWING CASES IN WAVE 1 OF)2:12-MD-02327 MDL 200:) MDL 2327 7) 8 Marty Babcock v. Ethicon, Inc.)JOSEPH R. GOODWIN Civil Action No. 2:12-cv-01052)U.S. DISTRICT JUDGE 9 Daphne Barker, et al. v.) Ethicon, Inc., et al.) 10 Civil Action No. 2:12-cv-00899) 11 Dorothy Baugher v. Ethicon,) Inc., et al.) 12 Civil Action No. 2:12-cv-01053) 13 Harriet Beach v. Ethicon,) Inc., et al.) 14 Civil Action No. 2:12-cv-00476) 15 Myra Byrd, et al. v. Ethicon,) Inc., et al.) 16 Civil Action No. 2:12-cv-00748) 17 Fran Denise Collins v.) Ethicon, Inc., et al.) 18 Civil Action No. 2:12-cv-00931) 19 Dennis W. Dixon, Estate of) Virginia M. Dixon,) 20 Deceased v. Ethicon, Inc., et al.) Civil Action No. 2:12-cv-01081) 21) 22 Lois Durham, et al. v.) Ethicon, Inc., et al.) Civil Action No. 2:12-cv-00760) 23) 24 Karen Forester, et al. v.) Ethicon, Inc., et al.)</p> | <p>1 Beverly Kivel v. Ethicon,) Inc., et al.) 2 Civil Action No. 2:12-cv-00591) 3 Cheryl Lankston v. Ethicon,) Inc., et al.) 4 Civil Action No. 2:12-cv-00755) 5 Heather Long v. Ethicon, Inc.,) et al.) 6 Civil Action No. 2:12-cv-01275) 7 Donna Massey, et al. v.) Ethicon, Inc., et al.) 8 Civil Action No. 2:12-CV-00880) 9 Angela Morrison, et al. v.) Ethicon, Inc., et al.) 10 Civil Action No. 2:12-cv-00800) 11 Maria Eugenia Quijano v.) Ethicon, Inc., et al.) 12 Civil Action No. 2:12-cv-00799) 13 Penny Rhynehart v. Ethicon,) Inc., et al.) 14 Civil Action No. 2:12-cv-01119) 15 Victoria Rock v. Ethicon,) Inc., et al.) 16 Civil Action No. 2:12-cv-00867) 17 Denise Sacchetti v. Ethicon,) Inc., et al.) 18 Civil Action No. 2:12-cv-01148) 19 Debra A. Schnering, et al. v.) Ethicon, Inc., et al.) 20 Civil Action No. 2:12-cv-01071) 21 Sheri Scholl, et al. v.) Ethicon, Inc.) 22 Civil Action No. 2:12-cv-00738) 23 Donna Shepherd v. Ethicon,) Inc., et al.) 24 Civil Action No. 2:12-cv-00967)</p> |
| Page 3 | Page 5 |
| <p>1 Shirley Freeman, et al. v.) Ethicon, Inc., et al.) 2 Civil Action No. 2:12-cv-00490) 3 Monica Freitas, et al. v.) Ethicon, Inc., et al.) 4 Civil Action No. 2:12-cv-01146) 5 Susan Guinn v. Ethicon, Inc.,) et al.) 6 Civil Action No. 2:12-cv-01121) 7 Wendy Hagans v. Ethicon, Inc.,) et al.) 8 Civil Action No. 2:12-cv-00783) 9 Beth Harter, et al. v. Ethicon,) Inc., et al.) 10 Civil Action No. 2:12-cv-00737) 11 Rocio Herrera-Nevarez v.) Ethicon, Inc., et al.) 12 Civil Action No. 2:12-cv-01294) 13 Mary Holzerland, et al. v.) Ethicon, Inc., et al.) 14 Civil Action No. 2:12-cv-00875) 15 Lois Hoy, et al. v. Ethicon,) Inc., et al.) 16 Civil Action. 2:12-cv-00876) 17 Myndal Johnson v. Ethicon,) Inc., et al.) 18 Civil Action No. 2:12-cv-00498) 19 Holly Jones, et al. v. Ethicon,) Inc., et al.) 20 Civil Action No. 2:12-cv-00443) 21 Debra Lynn Joplin v. Ethicon,) Inc., et al.) 22 Civil Action No. 2:12-cv-00787) 23 Margaret Kirkpatrick v.) Ethicon, Inc., et al.) 24 Civil Action No. 2:12-cv-00746)</p> | <p>1 Cindy Smith v. Ethicon, Inc.,) et al.) 2 Civil Action No. 2:12-cv-01149) 3 Cherise Springer, et al. v.) Ethicon, Inc., et al.) 4 Civil Action No. 2:12-cv-00997) 5 Margaret Stubblefield v.) Ethicon, Inc., et al.) 6 Civil Action No. 2:12-cv-00842) 7 Lisa Thompson, et al. v.) Ethicon, Inc., et al.) 8 Civil Action No. 2:12-cv-01199) 9 Mary Thurston, et al. v.) Ethicon, Inc., et al.) 10 Civil Action No. 2:12-cv-00505) 11 Shirley Walker, et al. v.) Ethicon, Inc., et al.) 12 Civil Action No. 2:12-cv-00873) 13 Cathy Warlick v. Ethicon,) Inc., et al.) 14 Civil Action No. 2:12-cv-00276) 15 Laura Waynick, et al. v.) Ethicon, Inc., et al.) 16 Civil Action No. 2:12-cv-01151) 17 Rebecca Wheeler, et al. v.) Ethicon, Inc., et al.) 18 Civil Action No. 2:12-cv-01088) 19 Nancy Williams v. Ethicon,) Inc., et al.) 20 Civil Action No. 2:12-cv-00511) 21 Thelma Wright v. Ethicon,) Inc., et al.) 22 Civil Action No. 2:12-cv-01090) 23) 24)</p> |

2 (Pages 2 to 5)

Golkow Technologies, Inc. - 1.877.370.DEPS

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 6</p> <p>1 APPEARANCES</p> <p>2</p> <p>3 FOR THE PLAINTIFFS:</p> <p>4 Michael H. Bowman, Esquire</p> <p>5 Wexler Wallace LLP</p> <p>6 55 West Monroe Street, Suite 3300</p> <p>7 Chicago, Illinois 60603</p> <p>8 312.346.2222</p> <p>9 mhb@wexlerwallace.com</p> <p>10</p> <p>11 FOR THE DEFENDANTS:</p> <p>12 Chad R. Hutchinson, Esquire</p> <p>13 Butler Snow, LLP</p> <p>14 1020 Highland Colony Parkway, Suite 1400</p> <p>15 Ridgeland, Mississippi 39157</p> <p>16 601.948.5711</p> <p>17 chad.hutchinson@butlersnow.com</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> | <p style="text-align: right;">Page 8</p> <p>1</p> <p>2 QUESTIONS INSTRUCTED NOT TO ANSWER</p> <p>3</p> <p>4 PAGE</p> <p>5 I understand that. But I'm -- my question 96</p> <p>6 is related to these 44 women. Can you tell</p> <p>7 us, to a reasonable degree of scientific</p> <p>8 certainty, whether or not the mesh, in any</p> <p>9 of these 44 women, ever oxidized?</p> <p>10</p> <p>11 I'm asking, Doctor, can it ever 162</p> <p>12 be completely -- can oxidation ever be</p> <p>13 completely eliminated?</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |
| <p style="text-align: right;">Page 7</p> <p>1 EXAMINATION</p> <p>2</p> <p>3 PAGE</p> <p>4 Examination by Mr. Hutchinson 9</p> <p>5</p> <p>6 EXHIBITS</p> <p>7</p> <p>8 PAGE</p> <p>9 Exhibit 1 Notice to Take Deposition 9</p> <p>10 Exhibit 2 Expert Report of Scott Guelcher, 10</p> <p>11 Ph.D., CV, Billing Information,</p> <p>12 Reliance List</p> <p>13 Exhibit 3 Abstract - Oxidative Degradation 28</p> <p>14 of Polypropylene</p> <p>15 Pelvic Mesh in Vitro</p> <p>16 Exhibit 4 Characterization of the host 44</p> <p>17 inflammatory</p> <p>18 response following implantation</p> <p>19 of prolapse</p> <p>20 mesh in rhesus macaque</p> <p>21 Exhibit 5 Blank Piece of Paper 113</p> <p>22 Exhibit 6 In vivo oxidative degradation of 130</p> <p>23 polypropylene pelvic mesh - Imel</p> <p>24 Exhibit 7 Seven Year Dog Study 166</p> <p>Exhibit 8 Stress-Strain Curve - Graph 179</p> | <p style="text-align: right;">Page 9</p> <p>1 SCOTT GUELCHER</p> <p>2 was called as a witness, and after having been</p> <p>3 first duly sworn, testified as follows:</p> <p>4</p> <p>5 (Whereupon Exhibit 1 was marked as an</p> <p>6 exhibit.)</p> <p>7</p> <p>8 EXAMINATION BY MR. HUTCHINSON:</p> <p>9 Q. Good morning, Dr. Guelcher. Chad</p> <p>10 Hutchinson, counselor for Ethicon.</p> <p>11 I'll hand you what we've marked as</p> <p>12 Exhibit 1 to your deposition. Have you seen that</p> <p>13 deposition notice before?</p> <p>14 A. Yes.</p> <p>15 Q. And did you bring any documents with</p> <p>16 you responsive to that deposition notice?</p> <p>17 A. I did not.</p> <p>18 MR. HUTCHINSON: Counsel, I understand</p> <p>19 you're producing a flash drive right now, more or</p> <p>20 less as we speak, that will contain what?</p> <p>21 MR. BOWMAN: It will contain everything</p> <p>22 he reviewed, and it is on his reliance list.</p> <p>23 MR. HUTCHINSON: And it will not</p> <p>24 contain any new testing; is that correct?</p> |

3 (Pages 6 to 9)

Golkow Technologies, Inc. - 1.877.370.DEPS

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 10</p> <p>1 MR. BOWMAN: There -- the testing 2 that's been done has been produced in the past. 3 There's nothing new produced today. 4 BY MR. HUTCHINSON: 5 Q. Dr. Guelcher, what are the names of the 6 products that you're -- you're here to give 7 testimony about? 8 A. I believe the SUI slings and the POP 9 devices that would include the GYNEMESH, the TVT, 10 TVT-O, is my understanding. I have to look at my 11 report for all the list of the names. 12 Q. Sure. And I'll hand you what we'll 13 mark as Exhibit 2 to your deposition. 14 A. Okay. 15 (Whereupon Exhibit 2 was marked as an 16 exhibit.) 17 THE WITNESS: That would help me. 18 MR. HUTCHINSON: Sure. Counsel. 19 MR. BOWMAN: Thank you. 20 THE WITNESS: Did you -- is there still 21 a question? 22 BY MR. HUTCHINSON: 23 Q. Yes, sir. 24 A. Oh.</p> | <p style="text-align: right;">Page 12</p> <p>1 Q. What does TVT-S stand for? 2 A. That's the -- the shorter sling, so 3 the -- the -- the TVT is a longer sling. The TVT-S 4 is shorter. 5 Q. Okay. And what does TVT-S stand for? 6 A. I -- I don't remember the meaning 7 behind the acronym right now. The TVT is a 8 transvaginal tape, but I don't -- I don't -- I 9 don't remember exactly what the S stands for right 10 now. 11 Q. Which -- which POP or pelvic organ 12 prolapse devices are you here to give testimony 13 about? Which specific ones? 14 A. Well, they're listed in the report, the 15 PROSIMA, the PROLIFT, and the GYNEMESH. 16 Q. Any others? 17 A. Those are the ones I can think of right 18 now. 19 Q. What about PROLIFT+M? Are you here to 20 give testimony today about PROLIFT+M? 21 A. Yes. The PROLIFT+M is also mentioned 22 in the report. That -- well -- okay. It's -- it's 23 a hybrid material that has the -- the MONOCRYL 24 polyester resin with the PROLENE. So that's in the</p> |
| <p style="text-align: right;">Page 11</p> <p>1 Q. I'm waiting for your answer. 2 A. Oh. 3 Well, as I stated in my report, these 4 are the SUI, stress urinary incontinence, and the 5 pelvic organ prolapse, POP, devices. This would 6 include PROSIMA, PROLIFT, GYNEMESH, the TVT 7 devices. All of these devices are made from 8 PROLENE. 9 Q. All right. Which specific SUI slings 10 are you here to give testimony about? 11 A. There's 200 cases in this wave. My 12 understanding is some of these are TVT, TVT-O. 13 Those are the ones I can remember right now. 14 My report was directed more toward the 15 polypropylene, PROLENE, polypropylene that's used 16 to make those devices. 17 Q. TVT and TVT-O are the only two names of 18 the products that you can remember for SUI devices? 19 A. There's a -- I'm sorry. There's a 20 TVT-S. Those are the ones that I can remember 21 right now. 22 Q. Okay. Can you remember any others? 23 A. I think that's what I can remember 24 right now.</p> | <p style="text-align: right;">Page 13</p> <p>1 report as well. 2 Q. And, Doctor, you're referring to 3 Exhibit 2, which is your expert report; is that 4 correct? 5 A. I am. 6 Q. Is this report complete and accurate? 7 A. Yes. 8 Q. Is this a final version? 9 A. Yes. I -- I -- I believe so. 10 Q. How many hours did you spend on this 11 report? 12 A. I -- I don't know. I don't -- I don't 13 track the hours. I don't -- I don't know how many 14 hours I spent. 15 Q. Okay. How do you bill the attorneys 16 for your time? 17 A. So that was a -- a billing sheet that I 18 believe I produced with the report, where we just 19 bill by the report. And this was, I believe, a -- 20 what I would call a medium report. 21 Q. What is a medium report? 22 A. It's -- in the billing, I just break it 23 down and do a short report, a medium, and a long 24 report. This one would have been in the medium</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 14</p> <p>1 category.</p> <p>2 Q. So would that be a flat fee for this</p> <p>3 report?</p> <p>4 A. That's correct.</p> <p>5 Q. What is the flat fee for this report</p> <p>6 that --</p> <p>7 A. It's \$10,000. Yeah.</p> <p>8 Q. Marked as Exhibit 2?</p> <p>9 A. That's correct.</p> <p>10 Q. And are all -- are all of the opinions</p> <p>11 that you intend to offer in this litigation</p> <p>12 contained in your expert report marked as Exhibit</p> <p>13 2?</p> <p>14 A. Yes, they are.</p> <p>15 Q. I've handed you, also, a CV, which is</p> <p>16 part of Exhibit 2.</p> <p>17 A. Yes.</p> <p>18 Q. Is that the most recent version of your</p> <p>19 CV?</p> <p>20 A. I believe so. I have to check it</p> <p>21 briefly. But I believe this is the -- this is the</p> <p>22 current version. Okay. Yes.</p> <p>23 Q. And your reliance list is also marked</p> <p>24 as Exhibit 2. Is that the most current reliance</p> | <p style="text-align: right;">Page 16</p> <p>1 with Dr. Iakovlev. I -- I wrote the paper with</p> <p>2 him, but. . . I guess I'm a little confused about</p> <p>3 the question.</p> <p>4 Q. Okay. So the question is I want you to</p> <p>5 talk about your opinions as they relate to pelvic</p> <p>6 organ prolapse products.</p> <p>7 A. Yes.</p> <p>8 Q. Have you discussed those opinions with</p> <p>9 anybody other than Dr. Dunn and Dr. Iakovlev?</p> <p>10 A. Not other than attorneys, I can't</p> <p>11 think. . .</p> <p>12 Q. Never spoken to any other scientist or</p> <p>13 medical doctor about those opinions; is that</p> <p>14 correct?</p> <p>15 A. So I -- I have presented at -- at</p> <p>16 meetings, the IUGA meeting last year in Nice.</p> <p>17 Q. And we're going to get to that --</p> <p>18 A. Okay.</p> <p>19 Q. -- but I want to talk about your</p> <p>20 opinions as they relate to pelvic organ prolapse</p> <p>21 products.</p> <p>22 A. Okay.</p> <p>23 Q. Have you discussed those with any</p> <p>24 scientist or medical doctor?</p> |
| <p style="text-align: right;">Page 15</p> <p>1 list?</p> <p>2 A. I believe so. Again, I'd like to check</p> <p>3 it for just a second. I believe so.</p> <p>4 Q. Okay. Doctor, other than attorneys,</p> <p>5 have you discussed your opinions, as they relate to</p> <p>6 pelvic organ -- pelvic organ prolapse products,</p> <p>7 with anyone else?</p> <p>8 A. With -- Dr. Dunn and I have been</p> <p>9 working together on this litigation with the</p> <p>10 attorneys.</p> <p>11 Q. And other than Dr. Dunn, have you</p> <p>12 discussed your opinions regarding pelvic organ</p> <p>13 prolapse products with anyone else?</p> <p>14 A. No. I'm sorry. Dr. Iakovlev.</p> <p>15 (Reporter interruption for</p> <p>16 clarification.)</p> <p>17 THE WITNESS: I'm sorry. Dr. Iakovlev,</p> <p>18 I-a-k-o-v-l- -- do you mean -- can I clarify? Do</p> <p>19 you mean in this specific report the opinions --</p> <p>20 like this --</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. (Indicating yes.)</p> <p>23 A. Are you talking about this specific</p> <p>24 report or -- yeah. I've not discussed this report</p> | <p style="text-align: right;">Page 17</p> <p>1 A. At the meeting there was some</p> <p>2 discussion among the meeting participants. But --</p> <p>3 Q. Was this -- excuse me.</p> <p>4 A. Sorry. Go ahead. Yeah.</p> <p>5 Q. Was this that meeting in France?</p> <p>6 A. Yeah. That's right.</p> <p>7 Q. Other than in France, have you ever</p> <p>8 discussed any of those opinions with anyone else?</p> <p>9 A. I've presented it at a meeting at -- at</p> <p>10 the American Institute of Chemical Engineers in the</p> <p>11 fall of 2014. Presented a talk there.</p> <p>12 Q. Your opinions as they relate to pelvic</p> <p>13 organ prolapse products?</p> <p>14 A. I don't -- you know, I don't know that</p> <p>15 we had the POPs in that talk. I think that was</p> <p>16 slings.</p> <p>17 Q. Okay.</p> <p>18 A. So we talked about polypropylene</p> <p>19 oxidation.</p> <p>20 Q. I understand that.</p> <p>21 A. Not necessarily about the POP devices.</p> <p>22 Q. Okay.</p> <p>23 A. I'm just trying to understand what</p> <p>24 you're asking.</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 18</p> <p>1 Q. Fair enough. My question, though, as 2 it relates to pelvic organ prolapse products, have 3 you discussed those opinions as they relate to 4 pelvic organ prolapse products with anyone else? 5 A. I -- I don't believe so. 6 Q. Doctor, have you -- have you ever told 7 any doctor at Vanderbilt that you have concerns 8 about the safety of polypropylene or PROLENE mesh? 9 A. I had some email correspondence with a 10 Vanderbilt OB/GYN. I had some -- we -- it wasn't 11 about -- it wasn't about opinions about the 12 products. It was about research on polypropylene 13 oxidation. But I haven't discussed my opinions 14 with them. 15 Q. Okay. Do you know how many doctors 16 practice medicine at Vanderbilt? 17 A. No. 18 Q. Have you ever told a doctor at 19 Vanderbilt that you believe PROLENE mesh degrades 20 via oxidation? 21 A. No. I haven't had the opportunity. 22 Q. Doctor, you -- your lawyers -- or a 23 lawyer sitting to the right of you is producing me 24 a flash drive with all the documents you have</p> | <p style="text-align: right;">Page 20</p> <p>1 Q. (Indicating yes.) 2 A. Okay. 3 Q. Do you -- do you remember that? It was 4 in September of 2015. 5 A. Yes. I think that's the last time I 6 was here. 7 Q. In fact, you were in the same seat. 8 A. Probably. I don't -- I don't remember. 9 Q. Do you remember -- have you been 10 deposed in any mesh litigation since September of 11 2015? 12 A. I don't believe so. 13 Q. Have you testified in any trials 14 regarding mesh litigation since 2000 -- since 15 September 2015? 16 A. There was a Boston Scientific trial in 17 Statesville, North Carolina, in October. 18 Q. And you testified live in that trial? 19 A. Live? 20 Q. (Indicating yes.) 21 A. Yes. 22 Q. Are you still active in the 23 professional societies of American Institute of 24 Chemical Engineers?</p> |
| <p style="text-align: right;">Page 19</p> <p>1 reviewed; is that correct? 2 A. That's right. 3 Q. And would those be internal Ethicon 4 documents, at least some of them? 5 A. Some of them are. Yeah. 6 Q. Have you ever signed a confidentiality 7 agreement with respect to the documents that you've 8 reviewed from Ethicon? 9 A. I can't remember. Probably. I don't 10 remember. 11 Q. Where would it be if you did? 12 A. I don't know. I don't know that I have 13 that agreement. 14 Q. Where would you look for it if you had 15 it? 16 A. Well, I would think the attorneys would 17 have it. I -- I don't -- I just don't know that 18 I've ever signed it. 19 Q. Do you remember being deposed in the 20 Mullins litigation? 21 A. Mullins? 22 Q. Mullins. It's the -- was -- it was 37 23 consolidated -- 24 A. It was consolidated in West Virginia?</p> | <p style="text-align: right;">Page 21</p> <p>1 A. Yes, I am. 2 Q. The Society for Biomaterials? 3 A. Yes. 4 Q. Research Society For Bone and Joint 5 Injectable Biomaterials? 6 A. Yes. 7 Q. I noticed that your expert report, 8 which is marked as Exhibit 2, doesn't include those 9 professional societies. Why not? 10 A. They're listed on my CV, which is part 11 of the report. I -- I don't know why. I just 12 didn't list them. 13 Q. Doctor, do you recall -- did you ever 14 read the deposition transcript from the Mullins 15 litigation? 16 A. I don't remember. I've -- I just don't 17 remember. 18 Q. Have any of your opinions changed since 19 you were deposed in the Mullins litigation? 20 A. No. 21 Q. What has been your total billing amount 22 that you have billed plaintiff attorneys since the 23 Mullins litigation? 24 A. Oh, in this particular case. I</p> |

Scott Guelcher

| Page 22 | Page 24 |
|---|--|
| <p>1 submitted a bill for the report, for 10,000 for the 2 medium report.</p> <p>3 Q. What about any charges for your time? 4 A. For this litigation? I don't think so. 5 Oh. No. This -- this is the only -- that was the 6 only one for this litigation.</p> <p>7 Q. Have you done any additional work since 8 the Mullins deposition regarding mesh? 9 A. What do you mean by "work"? Do you 10 mean testing or reading? I'm not sure what you 11 mean.</p> <p>12 Q. Well, any other work that you believe 13 is applicable to the mesh litigation since you were 14 deposed in Mullins in September 2015.</p> <p>15 A. I -- I've not done any -- any testing. 16 I've done more reading, research. But I've not 17 done any testing since that time.</p> <p>18 Q. What additional research have you done? 19 A. Reviewing the newer papers that were in 20 the report, reviewing the -- the Ethicon internal 21 documents, that sorts of activities.</p> <p>22 Q. The "newer papers" that you're 23 referring to, are those contained in your expert 24 report?</p> | <p>1 this question because it's a research project. 2 It's not part of these opinions in the litigation. 3 So it's -- I would call that a research project.</p> <p>4 Q. Is it a research project for 5 litigation? 6 A. Not necessarily. 7 Q. So who is sponsoring the research 8 project? 9 A. Well, this is part of the work, as an 10 academic, is finding funding to support the work, 11 so. . . I don't -- I don't have any funding for it 12 right now.</p> <p>13 Q. Okay. Are you -- but you're trying to 14 get funding for a research project? 15 A. I'm considering it, but I haven't done 16 anything definitive at this time.</p> <p>17 Q. Have you asked anybody specifically for 18 funding? 19 A. No. 20 Q. Have you asked any plaintiff lawyer for 21 funding of this research project? 22 A. No. 23 Q. Can you give me just a general idea of 24 the research project that you're contemplating?</p> |
| Page 23 | Page 25 |
| <p>1 A. I believe they are. Yes. That would 2 be -- yes, they are.</p> <p>3 Q. Have you published any additional 4 articles? 5 A. On polypropylene mesh? 6 Q. (Indicating yes.) 7 A. No. 8 Q. Do you have any pending? 9 A. No. 10 Q. Have you worked on any since? 11 A. No. 12 Q. The last paper that you authored 13 regarding mesh was the one with Dr. Iakovlev 14 entitled "Degradation of Polypropylene in Vivo"? 15 A. Yes. 16 Q. Doctor, as we sit here today, are you 17 planning on doing any additional testing of mesh? 18 A. I don't know at this time. There are 19 no definite plans. 20 Q. Are you considering any additional 21 testing of mesh? 22 A. I am. 23 Q. All right. What are you considering? 24 A. Well, I don't -- I can't really answer</p> | <p>1 A. I'm really not comfortable doing that. 2 Just -- I -- I need to -- I just -- I don't -- I 3 don't think that would be good.</p> <p>4 Q. Okay. Are you refusing to tell me? 5 A. "Refusing" is kind of a strong word. I 6 mean, I -- I don't want to discuss it in this 7 deposition. It's a research project that's outside 8 this litigation. So I -- to me it's not 9 something --</p> <p>10 Q. Does it -- 11 A. -- I -- I -- I would like to discuss 12 here. 13 Q. Does it relate to PROLENE mesh? 14 A. I don't know. I haven't -- I don't 15 know at this time. 16 Q. Does it relate to any of Ethicon's 17 products? 18 A. Again, at this time, I -- I don't know. 19 Q. Okay. 20 A. I haven't gotten that far. 21 Q. We talked about the IUGA meeting that 22 you went to in France -- 23 A. Yes. 24 Q. -- back in -- in the summer of last</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 26</p> <p>1 year; is that correct?</p> <p>2 A. That's right.</p> <p>3 Q. Have you attended any other</p> <p>4 professional meetings since then regarding mesh?</p> <p>5 A. Regarding mesh? No. Not that I can</p> <p>6 remember.</p> <p>7 Q. Were you ever reimbursed for your time</p> <p>8 going to France for this meeting by the plaintiffs'</p> <p>9 lawyers?</p> <p>10 A. No.</p> <p>11 Q. Did anybody ever compensate you for</p> <p>12 your time?</p> <p>13 A. So I -- I paid for my expenses</p> <p>14 through -- through a fund I have at Vanderbilt that</p> <p>15 I use for international travel.</p> <p>16 Q. There was some discussion, if I recall,</p> <p>17 about you submitting a research grant to the</p> <p>18 National Institution of Health regarding mesh with</p> <p>19 a Dr. Carey; do you remember that?</p> <p>20 A. Yes. And for the record, can I just --</p> <p>21 when you asked previously about who I have talked</p> <p>22 with, she would be one that I discussed -- I just</p> <p>23 forgot until you brought it up. Okay? I just --</p> <p>24 Q. That's fine.</p> | <p style="text-align: right;">Page 28</p> <p>1 Q. Were you talking to her about doing</p> <p>2 anything as it relates to mesh?</p> <p>3 A. I just don't remember what I talked to</p> <p>4 her about. It's been awhile, and I haven't really</p> <p>5 acted on it. So I just -- I have lots of</p> <p>6 discussions about new research projects. I -- I</p> <p>7 just don't remember.</p> <p>8 (Whereupon Exhibit 3 was marked as an</p> <p>9 exhibit.)</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. I understand. I'll hand you what we've</p> <p>12 marked as Exhibit 3 to your deposition.</p> <p>13 A. Okay.</p> <p>14 Q. This is the -- the paper that you</p> <p>15 presented on at the meeting in France; is that</p> <p>16 right?</p> <p>17 A. Let me review it for -- briefly.</p> <p>18 This -- this -- yes, this appears to be that</p> <p>19 abstract that I submitted to the IUGA, and then I</p> <p>20 presented on it at the IUGA meeting.</p> <p>21 Q. And what contribution did Dr. Dunn</p> <p>22 make?</p> <p>23 A. So Dr. Dunn did the FTIR and the SEM</p> <p>24 analysis. He and his student.</p> |
| <p style="text-align: right;">Page 27</p> <p>1 A. Yeah. For the record, Dr. Carey would</p> <p>2 be another person that I've talked with.</p> <p>3 Q. Okay. You can answer that question --</p> <p>4 A. I'm sorry. Okay. Ask the question</p> <p>5 again. I -- I -- I forgot.</p> <p>6 Q. You discussed an idea about submitting</p> <p>7 a research grant to the NIH regarding mesh with</p> <p>8 Dr. Carey; do you remember that?</p> <p>9 A. Vaguely. Yeah, I think it came up.</p> <p>10 Q. What is -- what was the topic?</p> <p>11 A. I don't remember.</p> <p>12 Q. What's the status of it?</p> <p>13 A. I haven't submitted anything.</p> <p>14 Q. Okay. But what's the status of it?</p> <p>15 A. What do you mean the status? Like --</p> <p>16 Q. Where does it stand?</p> <p>17 A. Well, as I was saying earlier, I just</p> <p>18 haven't been working on it and I haven't drafted</p> <p>19 anything. I haven't submitted anything. I</p> <p>20 just. . .</p> <p>21 Q. Was this the same research grant idea</p> <p>22 that we discussed earlier?</p> <p>23 A. I don't remember. I -- I don't</p> <p>24 remember what I was talking with her about doing.</p> | <p style="text-align: right;">Page 29</p> <p>1 Q. And what did -- what contributions were</p> <p>2 yours?</p> <p>3 A. So my contributions were more on the</p> <p>4 design of the experiment, the selection of the</p> <p>5 oxidative medium, the -- those would have been my</p> <p>6 contributions.</p> <p>7 Q. Do you have any current or pending</p> <p>8 experience with -- experiments with Dr. Dunn?</p> <p>9 A. I do not.</p> <p>10 Q. What about Dr. Iakovlev?</p> <p>11 A. I do not.</p> <p>12 Q. Do you have any current or pending</p> <p>13 experiments regarding mesh with anyone, as we sit</p> <p>14 here today?</p> <p>15 A. No. I do not.</p> <p>16 Q. Do you have any mesh explants in your</p> <p>17 custody or control?</p> <p>18 A. No.</p> <p>19 Q. What about any pristine mesh exemplars</p> <p>20 in your custody or control?</p> <p>21 A. No.</p> <p>22 Q. You don't have any mesh whatsoever</p> <p>23 available to you in your custody or control?</p> <p>24 A. No.</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 30</p> <p>1 Q. Do you still defer to Dr. Dunn on the</p> <p>2 interpretations of the FTIR spectra?</p> <p>3 A. I do.</p> <p>4 Q. And you disclosed this work in the</p> <p>5 Perry litigation, didn't you? That was for TVT</p> <p>6 ABBREVO?</p> <p>7 A. The ABBREVO would be another product.</p> <p>8 Yes.</p> <p>9 Q. And you attempted to rely on this paper</p> <p>10 in the Perry litigation, didn't you?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: I -- I just don't</p> <p>13 remember. It may have been on the -- on the -- on</p> <p>14 the reliance list, but I don't -- I know it came up</p> <p>15 in the deposition, but I deferred to Dr. Dunn for</p> <p>16 the experimental details in the deposition. That's</p> <p>17 what I remember.</p> <p>18 BY MR. HUTCHINSON:</p> <p>19 Q. Did you rely on this, Doctor, in</p> <p>20 forming your opinions in the Perry litigation</p> <p>21 regarding TVT ABBREVO?</p> <p>22 A. I don't believe so. I mean, my</p> <p>23 opinions have not changed in some time. So this</p> <p>24 was supplemental information that supported my</p> | <p style="text-align: right;">Page 32</p> <p>1 These were sutures. I -- I -- we did -- no. No.</p> <p>2 This was mesh. This was -- this was mesh. I -- I</p> <p>3 don't remember the actual product that we were -- I</p> <p>4 mean, it's been some time. I think there was a --</p> <p>5 I think there was -- I think it was -- there were</p> <p>6 definitely two Boston Scientific meshes, maybe the</p> <p>7 Pinnacle. There were slings. Maybe the TV -- I</p> <p>8 think the TVT, too.</p> <p>9 Q. So you used a TVT and a Pinnacle device</p> <p>10 in your work --</p> <p>11 A. Perhaps --</p> <p>12 Q. -- regarding oxidative degradation of</p> <p>13 polypropylene in pelvic mesh in vivo attached as --</p> <p>14 I mean, marked as Exhibit 3 to your deposition? Is</p> <p>15 that your testimony, sir?</p> <p>16 A. That's what I remember. I didn't -- I</p> <p>17 mean, I wasn't -- yeah, I wasn't -- I'd have to</p> <p>18 review this. But I believe it was a TVT and two</p> <p>19 Boston Scientific meshes that were included -- I</p> <p>20 just need to read -- can I read this again?</p> <p>21 Because I can't remember, you know, exactly --</p> <p>22 Q. Absolutely.</p> <p>23 A. This was written two years ago</p> <p>24 almost --</p> |
| <p style="text-align: right;">Page 31</p> <p>1 opinion, but -- and it was on the reliance list</p> <p>2 but -- I think it was. I just -- I can't remember</p> <p>3 the details.</p> <p>4 Q. Doctor, you relied on this work, that</p> <p>5 we've marked as Exhibit 3 to your deposition, in</p> <p>6 the Winebarger versus Boston Scientific litigation;</p> <p>7 is that correct?</p> <p>8 A. Winebarger? What product was this? I</p> <p>9 can't remember the names -- the plaintiff name.</p> <p>10 Q. It was a lawsuit styled Winebarger,</p> <p>11 W-i-n-b-a-r-g-e-r, versus Boston Scientific.</p> <p>12 A. That name just doesn't sound -- was it</p> <p>13 part of a wave? Was it -- I just don't remember</p> <p>14 the plaintiffs' names probably.</p> <p>15 Q. Do you recall relying on this work that</p> <p>16 was marked as Exhibit 3 in the Winebarger versus</p> <p>17 Boston Scientific litigation?</p> <p>18 A. I don't. Because I don't recall the</p> <p>19 litigation. I just -- I don't -- the -- the</p> <p>20 plaintiff's name is -- that doesn't sound familiar</p> <p>21 to me.</p> <p>22 Q. Okay. Doctor, when we look at Exhibit</p> <p>23 3, what product was used in your work?</p> <p>24 A. It's been some time. I don't remember.</p> | <p style="text-align: right;">Page 33</p> <p>1 Q. Absolutely.</p> <p>2 A. -- so I'm trying to remember exactly</p> <p>3 what I wrote.</p> <p>4 Q. And this was also presented a year ago,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. So if you'll read through it and</p> <p>8 tell me, sir, what the name of the products were</p> <p>9 that were used in this experiment.</p> <p>10 A. Okay. I can -- give me a minute</p> <p>11 to. . .</p> <p>12 Okay. So this was the mesh study.</p> <p>13 Again, it's not stated in the abstract, but -- let</p> <p>14 me just look at it again. (Reviews document.)</p> <p>15 Okay. I -- I believe it was the TVT</p> <p>16 and the Boston Scientific Advantage and Links,</p> <p>17 maybe. It's just been so long, I -- I can't</p> <p>18 remember the exact devices.</p> <p>19 Q. So the products that you used were from</p> <p>20 two different manufacturers, in this abstract; is</p> <p>21 that correct, sir?</p> <p>22 A. I believe so.</p> <p>23 Q. Was the TVT mechanically cut or laser</p> <p>24 cut?</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 34</p> <p>1 A. I don't remember.</p> <p>2 Q. How can you find out?</p> <p>3 A. Dr. Dunn would have all that</p> <p>4 information. He -- he had the mesh. He put it in</p> <p>5 the medium. He was the one that physically did the</p> <p>6 work. He and, I think, maybe one of his students</p> <p>7 did some of it, but he -- he's the one that had the</p> <p>8 exemplars and cut the samples and put them in the</p> <p>9 medium. I didn't do that. And so --</p> <p>10 Q. Okay.</p> <p>11 A. And I never had the mesh in my</p> <p>12 possession that I remember.</p> <p>13 Q. Oh, you didn't. So, Doctor, can you</p> <p>14 testify, to a reasonable degree of scientific</p> <p>15 certainty, that the two products that were used in</p> <p>16 this experiment were TVT and a Boston Scientific</p> <p>17 product?</p> <p>18 MR. BOWMAN: Object to form.</p> <p>19 THE WITNESS: Again, I'm going based on</p> <p>20 my memory.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I understand.</p> <p>23 A. And --</p> <p>24 Q. But I'd like for -- I'd like -- I need</p> | <p style="text-align: right;">Page 36</p> <p>1 working on it. We don't know what we're going to</p> <p>2 do yet. It's just -- you know, we have -- very</p> <p>3 busy, and it's -- I don't -- I don't know what the</p> <p>4 plan is. But I'm not relying on it because we</p> <p>5 haven't published it.</p> <p>6 Q. Okay. Any other reasons?</p> <p>7 A. No. That's the main reason. I -- I</p> <p>8 believe the Court likes to see published studies</p> <p>9 and that's --</p> <p>10 Q. Okay.</p> <p>11 A. -- that -- that's our plan.</p> <p>12 Q. But it's fair to say that you've</p> <p>13 written a paper that investigated oxidative</p> <p>14 degradation of polypropylene mesh in vitro using an</p> <p>15 oxidative medium and you're not relying on that</p> <p>16 work in this litigation?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: Can you repeat that? I'm</p> <p>19 sorry.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Yes.</p> <p>22 A. It was long.</p> <p>23 Q. It's fair to say that you've written a</p> <p>24 paper --</p> |
| <p style="text-align: right;">Page 35</p> <p>1 an answer, based upon a reasonable degree of</p> <p>2 scientific certainty. Can you testify today, to a</p> <p>3 reasonable degree of scientific certainty,</p> <p>4 regarding the specific names of the products used</p> <p>5 in this experiment?</p> <p>6 A. I mean, I believe, to a reasonable</p> <p>7 degree of scientific certainty, that's what we --</p> <p>8 that's what we used. That's what I remember. You</p> <p>9 know, I work closely with Dr. Dunn. Our offices</p> <p>10 are right beside each other. So, I mean, he --</p> <p>11 he -- that's what I believe he did.</p> <p>12 Q. Okay. And, Doctor, when you were</p> <p>13 deposed in September in the Mullins litigation, you</p> <p>14 didn't rely on this abstract for your opinions in</p> <p>15 that; is that correct?</p> <p>16 A. I don't believe so.</p> <p>17 Q. And you're not relying on the abstract</p> <p>18 that you published for your opinions in this</p> <p>19 litigation; is that correct?</p> <p>20 A. No, I'm not.</p> <p>21 Q. Okay. Why not?</p> <p>22 A. Well, we -- we -- we would like to</p> <p>23 publish it. And that's something -- that's part of</p> <p>24 what we're -- we -- we just -- we're -- we're</p> | <p style="text-align: right;">Page 37</p> <p>1 A. Okay.</p> <p>2 Q. -- that investigated oxidative</p> <p>3 degradation of polypropylene using an oxidated</p> <p>4 medium and you're not relying on it in this</p> <p>5 litigation; is that fair to say?</p> <p>6 A. I would say it's a submitted abstract.</p> <p>7 This is a submitted abstract. I wouldn't call this</p> <p>8 a paper. It's a published abstract, and it is peer</p> <p>9 reviewed but not like a paper. It's not -- I'm not</p> <p>10 relying on it.</p> <p>11 Q. And --</p> <p>12 A. And that -- go ahead.</p> <p>13 Q. What is the status of this work,</p> <p>14 Doctor?</p> <p>15 A. As I said, I -- I -- I don't know. We</p> <p>16 don't know what we're going to do with it yet.</p> <p>17 Q. When is the last time you talked to</p> <p>18 Dr. Dunn about this?</p> <p>19 A. I don't remember.</p> <p>20 Q. Has it been more than six months?</p> <p>21 A. Probably not. But I just don't -- I</p> <p>22 don't remember what we said about this. We</p> <p>23 haven't -- I haven't relied on it in the recent</p> <p>24 litigation in some time. And it's -- you know,</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 38</p> <p>1 it's just one of these unpublished studies that we 2 did, published an abstract, submitted at a meeting, 3 and just haven't followed up on it for the paper. 4 That's what I would say. 5 Q. Is this work finished? 6 A. Well, this study is finished. But when 7 you were asking me about research earlier, I -- I 8 mean, I -- I'm trying to be honest without 9 revealing, you know, what I consider to be, you 10 know, associated with my research being 11 confidential. But I don't know what we're going to 12 do next. 13 Q. Okay. But this study was finished, 14 correct? 15 A. This study is completed. Yes. 16 Q. Right. And this study was peer 17 reviewed in an abstract in the International 18 Urogynecology Journal, correct? 19 MR. BOWMAN: Object to form. 20 THE WITNESS: It was -- it was reviewed 21 for the meeting. I -- I wouldn't -- it's not -- 22 yes, it was reviewed. Okay. 23 BY MR. HUTCHINSON: 24 Q. And, Doctor, were the chemical</p> | <p style="text-align: right;">Page 40</p> <p>1 A. I think I just answered the question. 2 Q. You didn't. 3 A. I did. 4 Q. I need "yes" or "no," and then you can 5 answer. . . 6 A. I can't give you a yes or no because 7 I -- I feel like you're trying to put -- I need to 8 be very specific about what that medium is 9 simulating. 10 Q. Absolutely. 11 And my question to you, sir, is the 12 oxidative medium designed to represent the actual 13 in vivo conditions in the body? Yes or no? 14 A. But "actual in vivo conditions" is what 15 I'm hung up on. That's a very vague term. It 16 is -- it's meant to simulate the 17 microenvironment -- in vivo microenvironment that 18 the material is exposed to. That's what it's meant 19 to simulate. That's, I think, an answer to your 20 question. You're asking me -- that's my answer. 21 Q. Is that the best you can do? 22 A. That's the best I can do. I'm sorry. 23 I just -- I don't want to agree to some very 24 vaguely stated question.</p> |
| <p style="text-align: right;">Page 39</p> <p>1 conditions, to which you subjected the mesh, 2 intended to represent an actual in vivo condition 3 in the body? 4 A. So they were intended to simulate the 5 adherent macrophage pocket, the -- the space 6 between the adherent cell and the surface of the 7 material. 8 Q. I under -- 9 A. That's been published. Right? Yeah. 10 Q. I understand. But was it intended to 11 represent actual in vivo conditions in the body? 12 Yes or no? 13 A. Well, I thought I answered your 14 question. That would be the -- the -- it's 15 simulating that -- that situation where you have an 16 inherent macrophage attached to a biomaterial in 17 the body and there's a privileged microenvironment 18 between the cell and the material. And that medium 19 has been shown to -- published to simulate those 20 oxidative conditions between the cell and the 21 surface of the material. 22 Q. Are the chemical conditions intended to 23 represent actual in vivo conditions in the body, 24 sir? Yes or no?</p> | <p style="text-align: right;">Page 41</p> <p>1 Q. Doctor, do you write about in vivo 2 conditions in this abstract? 3 A. I'd have to read it again. (Reviews 4 document.) 5 Q. Let's look on the last page. 6 A. Okay. 7 Q. At the conclusion. "Oxidative 8 degradation of polypropylene pelvic mesh was 9 evidenced by chemical and physical changes under 10 simulated in vivo conditions." 11 A. Okay. 12 Q. Did you write that? 13 A. I wrote that. 14 Q. Okay. So my question to you, sir, are 15 the chemical conditions, to which you subjected the 16 mesh, intended to represent simulated in vivo 17 conditions in the body? Yes or no? 18 A. Yes. I wrote that. I stand by what I 19 wrote. 20 Q. All right. Since the Mullins 21 deposition, Doctor, have you done any work to 22 determine if oxidized polypropylene will stain? 23 A. Since the Mullins deposition last fall? 24 Q. Yes, sir.</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 42</p> <p>1 A. No.</p> <p>2 Q. Have you ever done any work in your</p> <p>3 life to determine if oxidized polypropylene will</p> <p>4 stain?</p> <p>5 A. No.</p> <p>6 Q. When is the last time you've spoken</p> <p>7 with Dr. Iakovlev?</p> <p>8 A. That's been some time. Maybe -- I need</p> <p>9 to think for a minute. Probably last summer at the</p> <p>10 meeting.</p> <p>11 Q. Doctor, are you aware of any literature</p> <p>12 that discusses the extent to which oxidized</p> <p>13 polypropylene traps and holds stain?</p> <p>14 A. Well, we discussed it in the paper with</p> <p>15 Dr. Iakovlev, but I -- I'm not aware, at this</p> <p>16 moment, off the top of my head, of another paper</p> <p>17 that would -- I'd have to look at the paper again.</p> <p>18 It's been some time.</p> <p>19 Q. You testified in the Mullins deposition</p> <p>20 that you've never done an XPS analysis. Does that</p> <p>21 remain true?</p> <p>22 A. I'd like to -- I've -- I've never</p> <p>23 physically done it myself. My students have done</p> <p>24 it. But I've never actually done the measurement.</p> | <p style="text-align: right;">Page 44</p> <p>1 any molecular weight testing of PROLENE?</p> <p>2 A. Well, I'm trying to -- I'm trying to</p> <p>3 answer. So -- I mean, I don't -- I mean, being a</p> <p>4 professor, I don't actually work in the lab. I</p> <p>5 have graduate students and a lab manager that do</p> <p>6 the work that we discuss, right? And I -- I'm --</p> <p>7 sort of direct of work, if you want to call it</p> <p>8 that.</p> <p>9 And what I -- what I was saying is that</p> <p>10 some time ago, a couple years at least, we --</p> <p>11 Dr. Dunn and I sent some samples to -- Dr. Dunn</p> <p>12 handled the samples -- to another laboratory to do</p> <p>13 molecular weight measurements. And whether PROLENE</p> <p>14 meshes -- you know, meshes made out of PROLENE were</p> <p>15 in those samples, I can't remember. It's been a</p> <p>16 long time. So. . .</p> <p>17 Q. Okay. And you don't know the results;</p> <p>18 is that correct?</p> <p>19 A. I don't remember the results.</p> <p>20 Q. Doctor, have you ever done any</p> <p>21 molecular weight testing of PROLENE explants?</p> <p>22 A. I don't think so. The samples -- no, I</p> <p>23 don't think so.</p> <p>24 (Whereupon Exhibit 4 was marked as an</p> |
| <p style="text-align: right;">Page 43</p> <p>1 Q. Have you ever done any molecular weight</p> <p>2 testing of PROLENE?</p> <p>3 A. Not of PROLENE.</p> <p>4 Oh, I'm sorry. Can I --</p> <p>5 Q. (Indicating yes.)</p> <p>6 A. We -- we did some molecular weight</p> <p>7 testing with Dr. Dunn on exemplars some time ago.</p> <p>8 It's been a long time. And I don't remember if</p> <p>9 PROLENE or TVT devices were included. I can't</p> <p>10 remember the devices.</p> <p>11 Q. Okay.</p> <p>12 A. But we -- we sent those to another lab.</p> <p>13 It was in one of his reports.</p> <p>14 Q. What were the results?</p> <p>15 A. I don't remember. I haven't been</p> <p>16 relying on that, so I just don't remember.</p> <p>17 (Reporter interruption for</p> <p>18 clarification.)</p> <p>19 THE WITNESS: You know, I'm. . .</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Well, my question --</p> <p>22 A. Yeah.</p> <p>23 Q. I'm not sure I understood your answer.</p> <p>24 Have you ever done -- have you personally ever done</p> | <p style="text-align: right;">Page 45</p> <p>1 exhibit.)</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, handing you what we'll mark as</p> <p>4 Exhibit 4 to your deposition --</p> <p>5 A. Okay.</p> <p>6 Q. -- you cite this on page 9 of your</p> <p>7 expert report. Do you remember that?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And, in fact, if you look on</p> <p>10 your expert report, under "Summary of Opinions,"</p> <p>11 Number 7.</p> <p>12 A. Okay.</p> <p>13 Q. It's on page 3. It states --</p> <p>14 A. Okay.</p> <p>15 Q. -- ". . .the use of heavy-weight meshes</p> <p>16 directly correlates with more exposure of</p> <p>17 polypropylene to the Foreign Body Reaction and</p> <p>18 greater changes after implantation. . ."</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. All right. Doctor, how do you define</p> <p>22 "heavy-weight"?</p> <p>23 A. My understanding is that the TVT mesh</p> <p>24 has a weight of around -- a surface density of</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 46</p> <p>1 around 100, would be a heavy-weight mesh. 2 Let me look at this paper again for a 3 minute. I believe it was discussed in here, the 4 densities of the specific meshes that she tested. 5 Yeah. So this would be the GYNEMESH 6 that had a density of 44 grams to square meter; 7 ULTRAPRO, which was 31; and Restorelle was 19. 8 Q. Doctor, how do you define 9 "heavy-weight"? 10 A. How do I define "heavy-weight"? 11 Q. Yes, sir. 12 A. I think -- I think something greater 13 than 50 grams per square meter would be a heavier 14 weight mesh. 15 Q. And how do you come up with the number 16 50 grams per square meter? 17 A. I -- I can't remember. There's some 18 papers -- there's a paper where this is -- these 19 are classified, and I just can't remember the 20 numbers right now. 21 Q. Well, you mean you can't remember the 22 cite right now? 23 A. Yeah. Well, the -- I can't remember 24 the citation, and I can't remember the actual</p> | <p style="text-align: right;">Page 48</p> <p>1 right? I mean, as the density increases, it's 2 going to be more intense. That's what I was 3 saying. 4 Q. Right. My question to you, sir, is how 5 do you define a heavy-weight mesh? Is it something 6 greater than 50 -- I'm sorry -- something greater 7 than a 100 grams per meter squared? Is that 8 Dr. Guelcher's definition? 9 MR. BOWMAN: Object to form. 10 THE WITNESS: Again, there's lots of 11 different definitions of polypropylene mesh. 100 12 grams per square meter is -- I would consider that 13 to be a heavy-weight mesh. 14 BY MR. HUTCHINSON: 15 Q. Okay. And if something is less than 16 100 grams per square metered, would that be a 17 medium-weight mesh or a light-weight mesh? What 18 would it be? 19 A. I don't -- I don't know specifically. 20 I mean, everybody has a different range that they 21 use to define that. I don't -- I mean, there's not 22 a lot of -- there's not a lot of agreement in the 23 literature. 24 Q. You can't tell me whether or not</p> |
| <p style="text-align: right;">Page 47</p> <p>1 ranges that were listed in the -- in the table. 2 I'd have to look at this -- 3 Q. I understand. But, Doctor, sitting 4 here today, and one of your opinions on Number 7 is 5 the -- is about heavy-weight meshes. So my 6 question to you is -- 7 A. Okay. 8 Q. -- how do you define a heavy-weight 9 mesh? 10 A. So a heavy-weight mesh would be a mesh 11 in the range of -- I'd probably say 100 grams per 12 square meter. Those are the heavy-weight meshes 13 that -- in my recollection. 14 Q. Okay. And if something is less than 15 100 grams per square meter, according to your -- 16 your definition, would that be a light-weight mesh? 17 A. No. I don't think I would call it a 18 light-weight mesh. I mean, what I was really 19 trying to say in this opinion is that the more 20 polypropylene is there, the more intense the 21 foreign body reaction. That's what the point of 22 that opinion is. 23 Q. Right. But my -- 24 A. So it's a sliding scale. I mean --</p> | <p style="text-align: right;">Page 49</p> <p>1 something would be a light-weight mesh if it was 2 less than 100 grams per meter squared; is that 3 correct? 4 A. Some would call that a -- a 5 light-weight mesh -- 6 Q. All right. 7 A. -- if it's less than 100. 8 Q. Do you -- do you, Doctor, as a polymer 9 scientist and as an expert in this litigation, have 10 a definition for a light-weight mesh? 11 A. No. Because I was looking at it from 12 the perspective of the amount of polypropylene 13 increases with mesh density. It's not just a 14 simple classification, as the mesh increases, the 15 foreign body reaction increases, because it's 16 dependent on that surface of polypropylene. That's 17 what I'm saying. 18 Q. Are you aware of any medical device 19 industry standard that measures or defines 20 heavy-weight mesh? 21 A. Industry standard? I -- I'm -- I -- I 22 think that's what I was saying. There's different 23 investigators and maybe companies who have 24 defined -- but it's -- it's not -- I don't -- I</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 50</p> <p>1 don't -- I guess what I'm saying is I don't 2 consider it a -- something that's agreed upon, say, 3 like in an ASTM standard. It's somewhat 4 discretionary, I would say. 5 Q. All right. So you're not aware of any 6 medical device industry standard that measures or 7 defines heavy-weight mesh; is that correct? 8 A. There may be a standard that mesh -- I 9 can't think of it right now. I -- I can't 10 remember. 11 Q. Okay. Doctor, are you aware of any 12 medical device industry standard that measures and 13 defines pore size? 14 A. I mean, pore size isn't really what I 15 was talking about in my opinions. So that's not 16 something -- 17 Q. All right. I can cut to the chase. 18 A. Okay. 19 Q. Do you have any opinions whatsoever 20 regarding the pore size of the PROLENE mesh 21 contained in any of the products that you're giving 22 opinions about today? 23 MR. BOWMAN: Object to form. 24 BY MR. HUTCHINSON:</p> | <p style="text-align: right;">Page 52</p> <p>1 discussing pore size in the report. 2 BY MR. HUTCHINSON: 3 Q. Okay. Well, Doctor, what is your 4 opinion regarding the ideal weight of mesh? 5 A. I don't believe I've expressed an 6 opinion about the ideal weight. My opinion has 7 been the more mesh, the more intense the foreign 8 body reaction. So I haven't really expressed an 9 opinion about ideal weight. 10 Q. Okay. Do you have an opinion, as we 11 sit here today, regarding the ideal mesh -- mesh in 12 terms of weight? 13 A. It would help me if you could be 14 specific. I -- I -- I'm not saying that there's an 15 ideal weight for the mesh. All I'm saying is that 16 the intensity of the foreign body reaction 17 increases with the weight density of the mesh. 18 That's -- and I'm not saying that that should be 30 19 or it should be 20. I'm saying that -- it's -- as 20 the amount of polypropylene increases, the 21 intensity of foreign body reaction. That's -- 22 that's what I'm saying. 23 Q. Okay. But can you tell us -- can you 24 tell us the ideal weight of the mesh?</p> |
| <p style="text-align: right;">Page 51</p> <p>1 Q. We can short circuit that. 2 A. Okay. Let me just think for a second. 3 So I -- I don't believe that I 4 discussed pore size in my report. 5 Q. Is it fair to say, Doctor, you have no 6 opinions regarding pore size of the mesh of the 7 products that you're here to give testimony about 8 today; is that right? 9 MR. BOWMAN: Object to form. 10 THE WITNESS: Maybe other than it could 11 change in the mechanical environment and in the 12 chemical changes that happen to the mesh, pore size 13 could change, that could affect infiltration. 14 BY MR. HUTCHINSON: 15 Q. Is that an opinion you're going to 16 stand by today? 17 A. I don't believe so. It's not in my 18 report. 19 Q. Okay. Thank you. 20 So fair so say you have no opinions 21 regarding pore size on the products that you're 22 designated to give testimony about today? 23 MR. BOWMAN: Object to form. 24 THE WITNESS: I think so. I'm not</p> | <p style="text-align: right;">Page 53</p> <p>1 A. No. I've not testified about an ideal 2 weight of mesh. 3 Q. Doctor, you'll agree that any implanted 4 material will elicit some form of foreign body 5 reaction or inflammatory response? 6 A. Yes. That's a foreign body reaction. 7 When a material is implanted, it induces and 8 elicits a foreign body reaction. 9 Q. And the microphage's response is an 10 essential component of tissue incorporation, 11 correct? 12 A. What do you mean by "essential"? I'm 13 not -- 14 Q. You must have a microphage response to 15 have tissue incorporation in the mesh, correct? 16 A. Well, macrophages infiltrate the mesh 17 like they do any foreign body. It just happens. 18 It's not -- it's not necessarily something that can 19 be controlled. It just happens. It's a foreign 20 body reaction. 21 Q. Let's look at the Moalli paper -- 22 A. Okay. 23 Q. -- that we've marked -- 24 A. Okay.</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 54</p> <p>1 Q. -- Exhibit 4. Are you there with me?</p> <p>2 A. I am.</p> <p>3 Q. This paper studied two meshes with</p> <p>4 PROLENE: GYNEMESH PS and ULTRAPRO; is that right?</p> <p>5 A. Yes. I believe so.</p> <p>6 Q. And this is the one of the newer papers</p> <p>7 that you're relying on; is that correct?</p> <p>8 A. It is.</p> <p>9 Q. What does GYNEMESH PS stand for?</p> <p>10 A. I -- I don't remember the PS. I know</p> <p>11 that the GYNEMESH is -- is -- I believe it's used</p> <p>12 in the POP kits. It's a lower-density mesh than</p> <p>13 the TVT. I don't know what the PS -- I'd have to</p> <p>14 look at the paper again. I don't. . .</p> <p>15 Q. All right. It's on page 1 under</p> <p>16 "Results," last paragraph. They compare ULTRAPRO</p> <p>17 with Restorelle --</p> <p>18 A. Uh-huh.</p> <p>19 Q. -- and GYNEMESH PS. Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. My question, Doctor, is what does the</p> <p>22 PS in GYNEMESH stand for?</p> <p>23 A. I -- I just don't remember.</p> <p>24 Q. Did you make any effort to find out?</p> | <p style="text-align: right;">Page 56</p> <p>1 Do you know if the mesh made in GYNEMESH PS is 100</p> <p>2 percent PROLENE?</p> <p>3 A. I mean, I believe it is. They -- they</p> <p>4 say the -- we sought to determine the predominant</p> <p>5 cell type within the area of implantation of the</p> <p>6 prototypical polypropylene mesh, GYNEMESH PS.</p> <p>7 Q. ULTRAPRO has an absorbable component,</p> <p>8 doesn't it?</p> <p>9 A. It's my understanding there's a</p> <p>10 resorbable polyester component. Wait a minute.</p> <p>11 Let me look at my report again. I can't. . .</p> <p>12 Yeah, so the PROLIFT, I know, has</p> <p>13 the -- the resorbable component. But she says</p> <p>14 these are polypropylene meshes in the objective.</p> <p>15 So that's what I read it, is that these are</p> <p>16 polypropylene meshes with different densities.</p> <p>17 That was what I understood to be the -- the purpose</p> <p>18 of this study.</p> <p>19 Q. Doctor -- Doctor, do you know the</p> <p>20 weight of the adsorbable component in ULTRAPRO?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: I -- I don't remember</p> <p>23 right now.</p> <p>24 BY MR. HUTCHINSON:</p> |
| <p style="text-align: right;">Page 55</p> <p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I don't remember. I was</p> <p>3 looking at the density in the table. I don't know</p> <p>4 the specific formulation of that --</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Do you know how GYNEMESH PS may be</p> <p>7 different than GYNEMESH?</p> <p>8 A. I -- I -- I -- I don't remember how</p> <p>9 it's different from GYNEMESH.</p> <p>10 Q. Do you have any idea, as we sit here</p> <p>11 today, what the PS stands for?</p> <p>12 MR. BOWMAN: Object to form. Asked and</p> <p>13 answered.</p> <p>14 THE WITNESS: I mean, it's a company</p> <p>15 acronym. I don't -- I don't know why they call it</p> <p>16 a GYNEMESH PS. I don't remember.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Do you know if it's 100 percent</p> <p>19 PROLENE?</p> <p>20 A. I'd have to look at this again. I</p> <p>21 can't remember. One of these was -- maybe it was</p> <p>22 the Restorelle that had a -- had a resorbable</p> <p>23 component I thought.</p> <p>24 Q. Right. Let's talk about GYNEMESH PS.</p> | <p style="text-align: right;">Page 57</p> <p>1 Q. Let's talk about the -- the products</p> <p>2 that you're designated for. I will represent to</p> <p>3 you, Dr. Guelcher, and also represent to the Court</p> <p>4 that you've been designated for -- to give opinions</p> <p>5 for TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT EXACT,</p> <p>6 PROSIMA, GYNEMESH PS, PROLIFT, and PROLIFT+M. Have</p> <p>7 you heard of all those products?</p> <p>8 A. I have.</p> <p>9 Q. Okay.</p> <p>10 THE WITNESS: Can we take a break for a</p> <p>11 few minutes? My stomach's a little bit -- is that</p> <p>12 okay?</p> <p>13 MR. HUTCHINSON: Yes, sir.</p> <p>14 THE WITNESS: Thank you.</p> <p>15 (Brief recess.)</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Dr. Guelcher, are you okay?</p> <p>18 A. Yeah. I'm okay.</p> <p>19 Q. All right. If you need to take another</p> <p>20 break, let me know. Okay?</p> <p>21 A. Okay. Thanks.</p> <p>22 Q. Doctor, do you know the weight of</p> <p>23 TVT-O?</p> <p>24 A. The weight? The density?</p> |

15 (Pages 54 to 57)

Golkow Technologies, Inc. - 1.877.370.DEPS

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 58</p> <p>1 Q. In grams -- yes. In grams per meter 2 squared. 3 A. I believe it's similar to the TVT, 4 which is around 100. 5 Q. What about TVT ABBREVO? 6 A. I think it's similar. I think it's 7 made from the same mesh. 8 Q. Do you -- but do you know the weight, 9 sir? 10 A. 100. 11 Q. Do you know the weight of TVT-SECUR? 12 A. Let me look back at my report. 13 Again -- well. . . (Reviews document.) 14 Yeah. So it's in my report. The -- 15 the -- those SUI devices, the slings, the TVT-S, 16 TVT ABBREVO, TVT-O, TVT are made from this 17 105-gram-per-square-meter mesh. So they're all 18 made from the same mesh, in my understanding. 19 Q. And -- and, Doctor, is it your 20 testimony for all TVT products the weight of the 21 mesh per meter squared is the same? 22 A. That's my understanding -- 23 Q. All right. Doctor -- 24 A. -- for the slings.</p> | <p style="text-align: right;">Page 60</p> <p>1 Q. The weight of the mesh and clinical 2 problems; is that correct? 3 A. Well, this wasn't really addressing 4 that question. The -- the relationship was between 5 the density of the mesh and the nature of the 6 inflammatory infiltrate. That was the question she 7 was looking at. It wasn't related. This was a 8 preclinical study, I believe. So it wasn't -- this 9 was in Rhesus macaque. So it wasn't -- 10 (Reporter interruption for 11 clarification.) 12 THE WITNESS: Rhesus macaque, which is 13 the -- it's a -- it's a primate. So it's not a 14 clinical study. 15 BY MR. HUTCHINSON: 16 Q. There were a number of limitations in 17 that study, weren't there? 18 A. So she has a paragraph in the 19 discussion about limitations of the study, which is 20 typical in scientific research. That's what we do. 21 Q. Okay. And, Doctor, if we look back at 22 your expert report -- 23 A. Okay. 24 Q. -- under "Summary of Opinions" --</p> |
| <p style="text-align: right;">Page 59</p> <p>1 Q. And, Doctor, for the POP products, do 2 you know the weight of the mesh per meter squared? 3 A. I don't remember them all. The 4 GYNEMESH is 45 grams per square meter. The -- the 5 PROLIFT+M, that's the one that's the blend, has the 6 resorbable polyester. After the polyester resorbs, 7 the density is 28. So it's probably, roughly, you 8 know, half, something in that range. So as the 9 polyester resorbs, the density goes down. 10 Q. And, Doctor, if we look at the Moalli 11 paper -- 12 A. Okay. 13 Q. -- that you have, the mesh didn't 14 oxidize after 12 weeks, did it? 15 A. Well, she wasn't testing for oxidation. 16 She was looking at the cellular response. So I 17 wouldn't say that it didn't oxidize. I just -- I 18 don't think she reported that it did. But I don't 19 know that she really did any testing for that. 20 Q. A causal relationship wasn't 21 established in that paper, was it, sir? 22 A. A causal relationship -- 23 Q. Correct -- 24 A. -- between what?</p> | <p style="text-align: right;">Page 61</p> <p>1 A. Okay. 2 Q. -- Number 1 -- 3 A. So we -- okay. Go ahead. Sorry. 4 Q. Number 1 discusses "polypropylene 5 reacts with molecular oxygen by autoxidation 6 outside the body at elevated temperatures, 7 resulting in chain scission and deterioration. . ." 8 Do you see that? 9 A. Yes. 10 Q. At what elevated temperatures outside 11 the body? 12 A. I have to look at the details again. 13 Temperatures above 100 C. That is 100 Celsius. 14 Q. And -- and what is the normal body 15 temperature in Celsius degrees of the human body? 16 A. 37. 17 Q. And what is autoxidation, Doctor? 18 A. Well, "autoxidation" is a term that 19 some use to describe the reactive -- the reaction 20 of the polypropylene with molecular oxygen at 21 elevated temperatures. 22 Q. And we don't have elevated temperatures 23 in the body, in vivo, do we, to the point where it 24 would autoxidate?</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 62</p> <p>1 MR. BOWMAN: Object to the form. 2 THE WITNESS: Well, the body 3 temperature is 37 degrees C. So that reaction with 4 molecular oxygen would be slow. I mean. . . 5 BY MR. HUTCHINSON: 6 Q. In fact, have you quantified how slow 7 it would be? 8 A. Well, I mean, Leibert addressed that 9 question with molecular oxygen. 10 Q. But my question to you, sir, is have 11 you personally quantified that? 12 A. No. Because I don't think it's 13 relevant because there's more reactive forms of 14 oxygen in the body that are causing the reaction. 15 So. . . 16 Q. What is -- what is required for PROLENE 17 to undergo autoxidation? 18 A. Well, PROLENE will undergo oxidation 19 with molecular oxygen. It -- it -- it can happen 20 at lower temperatures. It's just very, very slow. 21 Q. Okay. 22 A. So, I mean, it happens faster. Like 23 any chemical reaction -- 24 Q. I understand.</p> | <p style="text-align: right;">Page 64</p> <p>1 increases with temperature. 2 Q. Okay. 3 A. As the temperature gets higher, it gets 4 faster. 5 Q. Can you -- can you tell me a 6 temperature for PROLENE to undergo autoxidation? 7 Can you tell me a specific temperature? 8 MR. BOWMAN: Object to form. 9 THE WITNESS: Well, I'm trying to 10 answer. I -- I mean, it -- it's a chemical 11 reaction. And the Arrhenius equation tells us that 12 these reactions get faster as the temperature goes 13 up. So the reaction can occur at physiological 14 temperatures. It's just very slow. 15 People do the studies at higher 16 temperatures because they want to do them quickly. 17 So if you increase the temperature to 100 degrees 18 or 200 degrees Celsius, the reaction is faster. 19 And that's why a lot of these older studies did it 20 at higher temperatures. 21 BY MR. HUTCHINSON: 22 Q. Right. But my question is what 23 temperature is required for PROLENE to undergo 24 autoxidation?</p> |
| <p style="text-align: right;">Page 63</p> <p>1 A. -- it's -- it's faster at higher 2 temperatures. 3 Q. But what is required for PROLENE to 4 undergo autoxidation in the body? 5 A. In the body? You're asking a different 6 question. I'm confused. 7 Q. I am. 8 A. Okay. 9 Q. In general, what is -- strike that. 10 A. Okay. 11 Q. In general, what is required for 12 PROLENE to undergo autoxidation? 13 A. A -- I thought I answered it. It's -- 14 again, it would be the reaction with molecular 15 oxygen is happening at faster rates at higher 16 temperatures. 17 Q. Okay. 18 A. In -- in -- under body conditions, that 19 reaction with molecular oxygen would be slow. 20 Q. And -- 21 A. That's what I said. 22 Q. And at what temperature, Doctor, 23 would -- 24 A. Well, I mean, at what temperature -- it</p> | <p style="text-align: right;">Page 65</p> <p>1 A. I'm really trying to answer it. I 2 mean, it's a chemical reaction. It -- it -- it -- 3 PROLENE is polypropylene with antioxidants. And 4 the antioxidants can delay the reaction, but, 5 eventually, it's going to happen. So. . . 6 Q. At what rate -- excuse me. 7 A. Go ahead. I -- I'm finished. 8 Q. At what rate does PROLENE undergo 9 autoxidation in the body? 10 A. I don't know the rate. I've not 11 measured it. But I wasn't really -- no. I don't 12 know the rate that -- that thermal oxidation is 13 going to. . . 14 Q. If we -- if we look at the summary of 15 opinions, Number 3 -- 16 A. Okay. 17 Q. -- you discuss the dynamic environment 18 where polypropylene mesh is implanted. Do you see 19 that opinion? 20 A. Yes. 21 Q. What scientific evidence do you have, 22 Dr. Guelcher, for chain scission having occurred 23 with PROLENE in vivo? 24 MR. BOWMAN: Object to form.</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 66</p> <p>1 THE WITNESS: Well, I mean, the paper 2 published in 2015 by Mays, et al., showed 3 reductions in molecular weight. Now, that wasn't 4 PROLENE, but it was still polypropylene with 5 antioxidants. 6 BY MR. HUTCHINSON: 7 Q. Okay. 8 A. It's very similar material. 9 Q. Okay. Let's -- let's focus on PROLENE, 10 though, Doctor. 11 What scientific evidence do you have 12 for chain scission having occurred with PROLENE in 13 vivo? 14 MR. BOWMAN: Object to form. 15 THE WITNESS: PROLENE in vivo. I don't 16 know of a study that specifically looked at chain 17 scission of PROLENE in vivo. 18 BY MR. HUTCHINSON: 19 Q. And, Doctor, what scientific evidence 20 do you have for any PROLENE implant having oxidized 21 to produce a carbonyl group, a C double bond O? 22 A. Can we go back to the chain scission 23 one? I just remembered something or -- or I need 24 to answer this first.</p> | <p style="text-align: right;">Page 68</p> <p>1 cracking, and molecular weight degradation. 2 Q. Outside of Ethicon's internal 3 studies -- 4 A. Okay. 5 Q. -- are you aware of any scientific 6 evidence that a PROLENE implant has oxidized to 7 produce a carbonyl group? 8 MR. BOWMAN: Object to form. 9 THE WITNESS: So Clavé addressed -- 10 BY MR. HUTCHINSON: 11 Q. Okay. 12 A. No. Clavé didn't -- he didn't -- he 13 just says that he tested these different explants. 14 So he doesn't necessarily divide it out by 15 manufacturer, so it's -- 16 Q. I understand. 17 A. -- it's not totally clear, right? 18 Q. Okay. 19 A. But, I mean, he does say -- he does 20 observe evidence -- I've talked about this 21 before -- evidence in the FTIR spectrum that I 22 believe is indicative of oxidation. I know it's -- 23 we talked about this before. I don't -- 24 Q. Are you basing this solely on Clavé?</p> |
| <p style="text-align: right;">Page 67</p> <p>1 Q. Well, let's stick with this one. 2 A. Okay. So can you say it again? 3 Q. What scientific evidence do you have 4 for any PROLENE implant having oxidized to produce 5 a carbonyl group? 6 A. Let me look at my report again. There 7 was some studies done at Ethicon that reported 8 oxidation. And I'm trying to remember the details 9 of exactly what they reported. I -- I believe they 10 saw in those -- in those -- let me read my report 11 again because I'm -- I'm . . . (Reviews document.) 12 So there were some studies by Dr. Moy 13 that noted the presence of oxidation products by 14 FTIR. I believe that was incubated in hydrogen 15 peroxide. There were some human explants where 16 they observed degradation. And this question of 17 oxidation of the materials was referred to in those 18 studies. 19 Q. Okay. 20 A. They found that the cracked PROLENE 21 surface is a composite of oxidized polypropylene, 22 an adsorbed protein. So there was some internal 23 Ethicon studies that looked at these questions of 24 antioxidant depletion, oxidation of the surface,</p> | <p style="text-align: right;">Page 69</p> <p>1 A. Clavé would be the one that -- I think 2 Céline Mary discussed this as well. 3 Q. Okay. And is that the only scientific 4 evidence that you're relying on is Clavé and the 5 internal Ethicon documents for a PROLENE implant 6 having oxidized to produce a carbonyl group? 7 MR. BOWMAN: Object to form. 8 THE WITNESS: Those are the documents 9 that come to mind that I've testified about before. 10 BY MR. HUTCHINSON: 11 Q. Okay. Doctor, do you have -- and let's 12 talk about -- my question is very specific as it 13 relates to the nine specific products that you're 14 here to give testimony about. 15 A. Okay. 16 Q. TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT 17 EXACT, PROSIMA, GYNEMESH PS, PROLIFT, and 18 PROLIFT+M. Okay? 19 A. Yes. 20 Q. So my question, when I talk about the 21 nine products, that's what I'm talking about. 22 A. I understand. 23 Q. All right. Do you have any scientific 24 evidence that any of those nine products were</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 70</p> <p>1 implanted and oxidized to produce a carbonyl group?</p> <p>2 A. Again, the only study that could have</p> <p>3 included those devices would be the Clavé study</p> <p>4 where he took the 100 explants. And also the study</p> <p>5 with Dr. Iakovlev, but that was looking more at --</p> <p>6 that was explanted mesh as well, that looked at the</p> <p>7 degradation layer. But not -- well, he did look at</p> <p>8 the question of oxidation indirectly with the</p> <p>9 myeloperoxidase staining that we saw.</p> <p>10 Q. Right. But not specifically for those</p> <p>11 nine products, correct?</p> <p>12 A. Those nine products were not</p> <p>13 specifically mentioned in the Iakovlev study that I</p> <p>14 remember.</p> <p>15 Q. Thank you.</p> <p>16 So the only -- the only paper that</p> <p>17 you're relying on as it relates to whether any of</p> <p>18 those nine products oxidized to produce a carbonyl</p> <p>19 group, after it was implanted in vivo, is the Clavé</p> <p>20 study; is that correct?</p> <p>21 MR. BOWMAN: Object to form.</p> <p>22 THE WITNESS: For those nine products,</p> <p>23 that would be the one that I would. . .</p> <p>24 BY MR. HUTCHINSON:</p> | <p style="text-align: right;">Page 72</p> <p>1 Iakovlev study, we -- there were a lot of explants,</p> <p>2 but they weren't specifically named. They were</p> <p>3 slings, POPs, maybe some hernia mesh, too. But</p> <p>4 they -- the products weren't specifically named.</p> <p>5 So I -- I -- I can't -- I mean, it was a number of</p> <p>6 devices, right?</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. Yeah.</p> <p>9 A. Not -- not -- those specific products</p> <p>10 were not named.</p> <p>11 Q. Right. So I'm not asking about whether</p> <p>12 or not Iakovlev named them. My question to you,</p> <p>13 sir, is do you have any scientific evidence that</p> <p>14 any of those nine products have become embrittled</p> <p>15 in vivo?</p> <p>16 MR. BOWMAN: Object to form.</p> <p>17 THE WITNESS: Again, not direct -- what</p> <p>18 did you say? Embrittled? I mean, there's no</p> <p>19 direct evidence that those specific products has</p> <p>20 been published.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. And nor do you have any scientific</p> <p>23 evidence that any of those nine products have</p> <p>24 become embrittled, do you?</p> |
| <p style="text-align: right;">Page 71</p> <p>1 Q. That would be the one that you would</p> <p>2 what?</p> <p>3 A. I'm just thinking. I'm sorry. I'm</p> <p>4 just thinking. You're -- you're referring</p> <p>5 specifically to the question of the carbonyl bond</p> <p>6 and the oxidation, right?</p> <p>7 Q. (Indicating yes.)</p> <p>8 A. Yeah. That would be the one that would</p> <p>9 come to mind.</p> <p>10 Q. Okay.</p> <p>11 A. That's the one I would rely on.</p> <p>12 Q. Okay. And Clavé is the same one that</p> <p>13 you rely on that states that the FTIR could</p> <p>14 neither -- neither confirm nor rule out oxidation,</p> <p>15 correct?</p> <p>16 A. Clavé states that.</p> <p>17 Q. Yes.</p> <p>18 A. I don't necessarily agree with it. But</p> <p>19 that's what the paper says.</p> <p>20 Q. And, Doctor, going back to these nine</p> <p>21 products, do you have any evidence that any of</p> <p>22 these nine products became embrittled in vivo?</p> <p>23 MR. BOWMAN: Object to form.</p> <p>24 THE WITNESS: I mean, again, in the</p> | <p style="text-align: right;">Page 73</p> <p>1 MR. BOWMAN: Object to form.</p> <p>2 THE WITNESS: I guess I'm a little hung</p> <p>3 up on scientific evidence. I mean, you mean</p> <p>4 directly measured, right? Reported?</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. (Indicating yes.)</p> <p>7 A. I mean, I believe -- well, you know my</p> <p>8 opinions. But I --</p> <p>9 Q. Well, I'm trying to find out your</p> <p>10 opinions.</p> <p>11 A. Okay.</p> <p>12 Q. So my opinions are -- that's the goal</p> <p>13 of today.</p> <p>14 A. No. I understand. But -- okay. So</p> <p>15 I'll state it again. I mean, I believe -- I don't</p> <p>16 want to argue about it. I mean, I believe that</p> <p>17 those devices are made of polypropylene, which</p> <p>18 these fundamental chemical reactions apply to.</p> <p>19 Now, has anyone specifically measured it for those</p> <p>20 devices? I -- I -- I don't know that that's been</p> <p>21 reported, but I believe the body of scientific</p> <p>22 evidence says that that's what's happening. That's</p> <p>23 my opinion. Okay?</p> <p>24 Q. But my question to you, do you know of</p> |

Scott Guelcher

| Page 74 | Page 76 |
|--|---|
| <p>1 any scientific evidence, as we sit here today, that 2 any of those nine products have become embrittled 3 in vivo? 4 A. Again, I'm hung up on the scientific 5 evidence. I mean, I -- I believe there's 6 evidence -- 7 MR. BOWMAN: Object to the form. 8 THE WITNESS: Okay. 9 I don't know how to answer that. I 10 mean, I -- 11 BY MR. HUTCHINSON: 12 Q. Have you ever used the word "scientific 13 evidence" as a polymer scientist? 14 A. Well, I mean, it's a word. I mean, I 15 know this word. But it can mean lots of things to 16 lots of people, right? 17 Q. Okay. 18 A. Like anything. 19 Q. So my -- 20 A. So I -- I'm just -- I'm just saying 21 like a direct measurement of that phenomenon, 22 I've -- I've not seen published. 23 Q. Okay. You've not seen published it. 24 A. Yeah.</p> | <p>1 evidence that any of those nine specific products 2 have lost molecular weight in vivo? 3 A. Again, no direct measurements of that. 4 Q. And, Doctor, are you aware -- other 5 than Clavé, are you aware of any literature that 6 shows PROLENE produced a carbonyl group after it 7 was implanted? 8 A. Let me look at my report again. I know 9 Mary was looking at -- Céline Mary did the PROLENE 10 implant study with Guidoin. 11 (Reporter interruption for 12 clarification.) 13 THE WITNESS: Guidoin, G-u-i-d-o-i-n. 14 I just need to review what I wrote about that. 15 (Reviews document.) 16 Could you repeat the question? I'm -- 17 I'm sorry. I'm -- I'm not feeling well. I forgot 18 it. I -- could you repeat the question, please? 19 Oh, you're going to read it? Okay. 20 That's fine. 21 BY MR. HUTCHINSON: 22 Q. I can remember it. Other than Clavé, 23 are you aware of any literature that shows PROLENE 24 produced a carbonyl group after it was implanted?</p> |
| Page 75 | Page 77 |
| <p>1 Q. Nor are you aware of any evidence that 2 any of those nine products, specific products, have 3 become embrittled in vivo, are you? 4 MR. BOWMAN: Object to form. 5 THE WITNESS: Again, I've not seen 6 anybody actually measure that, I mean, if that's 7 what you're. . . 8 BY MR. HUTCHINSON: 9 Q. And you haven't measured that, have 10 you? 11 A. No. 12 Q. And, Doctor, are you aware of any 13 scientific evidence that any of those nine products 14 have lost molecular weight in vivo? 15 MR. BOWMAN: Object to form. 16 THE WITNESS: For those nine specific 17 products, no one has shown -- published that they 18 lose molecular weight. 19 BY MR. HUTCHINSON: 20 Q. And are you aware, personally, of any 21 evidence that any of those nine specific products 22 have lost molecular weight in vivo? 23 A. Could you rephrase that? I didn't -- 24 Q. Are you personally aware of any</p> | <p>1 A. Okay. I just need to find where I 2 wrote about Céline Mary to answer that question. 3 (Reviews document.) 4 Q. But you would -- but other than Céline 5 Mary, are you aware of any literature? 6 A. Carbonyl and PROLENE due to oxidation. 7 Q. After it was implanted. 8 A. After it was implanted -- 9 Q. Yes, sir. 10 A. -- in PROLENE. (Reviews document.) I 11 can't think of anything other than those two 12 studies. 13 Q. Doctor, have you ever examined an 14 explant of PROLENE from a patient? 15 A. With Dr. Dunn, yes. And Dr. Iakovlev. 16 Q. Was it -- what type of PROLENE explant 17 was it? 18 A. Oh, PROLENE. 19 Q. Oh, I'm sorry. Maybe you might -- 20 might not have understood my question. 21 A. I -- I -- 22 Q. Let's make sure the record's clear. 23 A. I miss -- yeah. 24 Q. That's fine. Don't worry about it.</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 78</p> <p>1 Have you ever examined a PROLENE 2 explant from a patient? 3 A. Not specifically PROLENE. 4 Q. Sitting here today, do you have any 5 evidence that a PROLENE explant has failed in the 6 patient? 7 MR. BOWMAN: Object to the form. 8 THE WITNESS: Wow. Failed. What do 9 you mean by "failed"? That's a -- could mean a lot 10 of things. So what do you mean -- can you be more 11 specific about failed? 12 BY MR. HUTCHINSON: 13 Q. It didn't do what it was intended to 14 do. 15 MR. BOWMAN: Object to form. 16 THE WITNESS: Are you talking about 17 mesh or sutures? I'm -- I -- it just seems like a 18 broad question. 19 BY MR. HUTCHINSON: 20 Q. Right. 21 A. If you could -- 22 Q. You're here about -- you're here about 23 nine mesh products, correct? 24 A. Yes.</p> | <p style="text-align: right;">Page 80</p> <p>1 on in the report, right? It was more what happens 2 to polypropylene. So there are studies that -- you 3 know, I mean, the Clavé study is these meshes -- 4 you know, they were explanted because they failed 5 so. . . 6 Q. Can you tell us the name of a patient 7 whose product did not work as intended? 8 A. I mean, I didn't even -- I didn't look 9 at patient records. I'm not a medical doctor. 10 My -- my -- my report was focused on what happens 11 to polypropylene that's implanted in the body and 12 if there are -- 13 Q. And you can't tell us the name of 14 somebody whose product has failed once it's in the 15 body, correct? 16 A. Well, I mean, I know that there's a -- 17 you know, the Huskey case, the Edwards case. I 18 mean, these patients had complications associated 19 with the mesh. So those are -- those are the cases 20 that I have worked on. 21 Q. Doctor, let's talk about 22 biocompatibility. 23 A. Okay. 24 Q. You'll agree that Ethicon performed</p> |
| <p style="text-align: right;">Page 79</p> <p>1 Q. All right. 2 A. Because you keep saying PROLENE and 3 mesh. I'm just getting confused. 4 Q. All right. Have you ever examined -- 5 strike that. 6 Do you have any scientific evidence 7 that any of the nine products that you're giving 8 testimony about today have failed in vivo? 9 MR. BOWMAN: Object to form. 10 THE WITNESS: I mean, that's why 11 there's a lawsuit because there's an injury because 12 of the device. So, I mean, I'm not focusing on the 13 clinical aspects of that. I -- I guess I really 14 don't understand what you're asking me. 15 BY MR. HUTCHINSON: 16 Q. Are you aware of any evidence that a 17 patient's mesh, from any of the nine products -- 18 A. Yeah. 19 Q. -- failed to do what it was intended to 20 do? 21 A. I mean, I know there are clinical 22 studies that have looked at this, but I just -- I 23 don't -- I mean, I have to look at -- I can't 24 remember -- I mean this wasn't what I was focusing</p> | <p style="text-align: right;">Page 81</p> <p>1 biocompatibility testing for the PROLENE -- 2 A. If you could be a little more specific. 3 You mean ISO 10993 testing? 4 Q. (Indicating yes.) 5 A. Yeah. This is standard for any -- any 6 biomedical device. 7 Q. Do you have any criticisms of the 8 biocompatibility testing that Ethicon did for any 9 of the nine products? 10 A. I've not testified about the ISO 10993 11 biocompatibility testing, other than it's in my 12 report that I -- I believe they should have done 13 some of this testing with the oxidative medium, but 14 that's -- that's not necessarily part of the -- I 15 mean, there's -- there's a -- there are some tests 16 on degradation with ISO 10993, but that medium is 17 typically not used. My testimony has been that 18 they should have looked at that. 19 But I've not critiqued -- I've not 20 expressed opinions about whether that -- could you 21 repeat your question? I -- I'm sorry. 22 Q. Well, do you have any criticisms -- 23 A. Criticism -- 24 Q. -- of Ethicon's biocompatibility</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 82</p> <p>1 testing of the PROLENE contained in any of the nine</p> <p>2 products, other than the oxidative opinions that</p> <p>3 you're --</p> <p>4 A. I've not discussed the ISO testing in</p> <p>5 my report. I've not opined on that.</p> <p>6 Q. But my question is, yes or no, do you</p> <p>7 have any opinions, other than the oxidative</p> <p>8 opinions that you're giving, regarding the</p> <p>9 biocompatibility testing of any of the nine</p> <p>10 products?</p> <p>11 A. No. It's not in my report. I've not</p> <p>12 discussed it.</p> <p>13 Q. You stated earlier that you have</p> <p>14 inspected mesh explants with Dr. Dunn.</p> <p>15 A. I've seen mesh -- mesh explants with</p> <p>16 Dr. Dunn and Dr. Iakovlev.</p> <p>17 Q. What products were those explants from?</p> <p>18 A. I believe it was an AMS mesh. I don't</p> <p>19 remember the -- it was -- I think it was POP, but I</p> <p>20 can't remember the exact device name.</p> <p>21 Q. AMS, American Medical Systems?</p> <p>22 A. That's right.</p> <p>23 Q. Have you ever inspected a PROLENE mesh</p> <p>24 explant from any of the nine products that we're</p> | <p style="text-align: right;">Page 84</p> <p>1 A. Seen these specific products?</p> <p>2 Q. Yes, sir.</p> <p>3 A. I've seen, I believe, the TVT, the</p> <p>4 TVT-O, the TVT-S, the ABBREVO because of previous</p> <p>5 litigation. The POP kits, I can't remember.</p> <p>6 Q. Have you ever seen TVT EXACT?</p> <p>7 A. I don't remember.</p> <p>8 Q. You don't remember if you've ever seen</p> <p>9 PROSIMA, GYNEMESH PS, PROLIFT or PROLIFT+M?</p> <p>10 A. Not those specific -- I mean, I've seen</p> <p>11 POP devices, but I -- I -- I can't remember, you</p> <p>12 know, who exactly they were manufactured by.</p> <p>13 Q. Have you ever held any of these</p> <p>14 products, these nine different products in your</p> <p>15 hand?</p> <p>16 A. Well, I mean, the -- the slings, the</p> <p>17 TVT, yeah. I've seen them and. . .</p> <p>18 Q. I'm sorry?</p> <p>19 A. Yeah, I mean, I've held them, stretched</p> <p>20 them, you know, these kinds of things.</p> <p>21 Q. Where?</p> <p>22 A. With Dr. Dunn at Vanderbilt. I mean,</p> <p>23 the testing that he did, right? So --</p> <p>24 Q. Does Dr. Dunn still has these exemplars</p> |
| <p style="text-align: right;">Page 83</p> <p>1 here today about?</p> <p>2 MR. BOWMAN: Objection. Asked and</p> <p>3 answered.</p> <p>4 THE WITNESS: I've seen -- I -- in</p> <p>5 visiting Dr. Iakovlev with plaintiff's counsel a</p> <p>6 few years ago, I looked at a number of mesh. I</p> <p>7 don't remember him identifying any of those as</p> <p>8 PROLENE, but I've -- I've -- I've seen those</p> <p>9 explanted meshes.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. But you've never seen an explanted</p> <p>12 PROLENE mesh from any of the nine products,</p> <p>13 correct?</p> <p>14 A. Perhaps. I just -- I -- I don't know</p> <p>15 if it was PROLENE or not.</p> <p>16 Q. You can't tell us about it, sitting</p> <p>17 here today; is that right?</p> <p>18 A. No.</p> <p>19 Q. And you've never done any testing of a</p> <p>20 PROLENE mesh explant from any of the nine products,</p> <p>21 correct?</p> <p>22 A. Not from these nine products. Right.</p> <p>23 Q. Doctor, going to these nine products,</p> <p>24 have you ever seen these?</p> | <p style="text-align: right;">Page 85</p> <p>1 that you handled --</p> <p>2 A. I don't know. I'm sorry. I don't</p> <p>3 know. I don't know what he has right now.</p> <p>4 Q. But you've never retained a PROLENE</p> <p>5 exemplar, have you?</p> <p>6 A. I have not.</p> <p>7 Q. Do you know how long any of these nine</p> <p>8 products have been on the market?</p> <p>9 A. Well, the TVT has been out for a while,</p> <p>10 since the '90s. I -- I don't remember the exact</p> <p>11 dates they were introduced. But the TVT was the</p> <p>12 first.</p> <p>13 Q. Do you know the physical dimensions of</p> <p>14 any of these products?</p> <p>15 A. No. No, I don't.</p> <p>16 Q. Do you know how many newtons of force</p> <p>17 are placed on the mesh from any of these nine</p> <p>18 products once -- once they're implanted in vivo?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: There are some studies</p> <p>21 that have looked at that. I don't -- I didn't</p> <p>22 really discuss that in this report. So I don't</p> <p>23 remember what those forces are. But there have</p> <p>24 been some studies that looked at the force on a</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 86</p> <p>1 sling. And I'm familiar with some of those 2 studies. 3 BY MR. HUTCHINSON: 4 Q. Do you -- do you know -- well, do you 5 have any opinions -- strike that. 6 You're not an expert in the 7 manufacturing process of PROLENE, pelvic mesh, are 8 you? 9 A. Manufacturing PROLENE? I'm -- I'm not 10 expressing opinions about the specific 11 manufacturing process. 12 Q. Are these meshes -- are they woven or 13 are they knitted for the nine different products? 14 A. For the nine products? 15 MR. BOWMAN: Object to form. 16 THE WITNESS: Could you explain what 17 you mean by woven versus knitted? That's kind of 18 a -- 19 BY MR. HUTCHINSON: 20 Q. Getting deep? 21 A. I mean, what do you mean by "woven"? I 22 mean, is it like -- 23 Q. Can you answer the question as it's 24 phrased?</p> | <p style="text-align: right;">Page 88</p> <p>1 correct? 2 A. Well, the -- yeah, the composition's 3 different because it has these additives. 4 MR. HUTCHINSON: I'm sorry. Did he say 5 "well, yeah"? 6 (Whereupon the previously mentioned 7 answer was read back by the reporter.) 8 THE WITNESS: I probably said -- yes, 9 it's -- it has additives. 10 BY MR. HUTCHINSON: 11 Q. Doctor, turn to Exhibit 1. I'll 12 represent to you and the Court that there are 44 13 different plaintiffs named on the notice of 14 deposition, starting with Marty Babcock -- 15 A. Okay. 16 Q. -- and ending with Thelma Wright. 17 That's 44 different cases. 18 A. I see. 19 Q. Did you know you were designated in 44 20 cases in this litigation? 21 A. I -- I didn't know the exact number of 22 44. I knew it was a wave. So I knew there were a 23 number of cases, but I wasn't familiar with the 24 specific plaintiffs because I'm not giving</p> |
| <p style="text-align: right;">Page 87</p> <p>1 MR. BOWMAN: Object to form. 2 THE WITNESS: I'd have to refresh 3 myself with the documents. I -- I -- I can't 4 remember them. 5 BY MR. HUTCHINSON: 6 Q. And as a material scientist, you'll 7 agree that PROLENE has a different chemical 8 composition than pure polypropylene, correct? 9 A. So PROLENE has two antioxidants, one 10 designed to prevent oxidation during 11 high-temperature processing, another during 12 storage. There are flow additives designed to make 13 extrusion easier, calcium stearate, some 14 surfactants. So there's other additives in there, 15 but those additives are added mainly for 16 manufacturing, in my understanding. 17 Q. Right. But PROLENE has a chemical 18 different composition -- strike that. 19 PROLENE has a different chemical 20 composition than pure PROLENE, correct? 21 MR. BOWMAN: Object to form. 22 BY MR. HUTCHINSON: 23 Q. I'm sorry. PROLENE has a different 24 chemical composition than pure polypropylene,</p> | <p style="text-align: right;">Page 89</p> <p>1 plaintiff-specific opinions. 2 Q. Do you know what products any of these 3 44 different women received? 4 A. No. As I said, I didn't review the 5 medical records. I'm -- I'm discussing -- my 6 opinions are all related to PROLENE and 7 polypropylene in -- in the body. Yes. 8 Q. And you don't know any of the implant 9 or explant dates for any of these women, correct? 10 A. I don't. I haven't reviewed that. 11 Q. And do you know the reason why any of 12 these women had their mesh removed? 13 A. Again, it's not -- I haven't reviewed 14 their clinical records, medical records, so I 15 wouldn't know. 16 Q. Do you even -- do you even know if any 17 of these women had their mesh removed? 18 A. I know that some of them do because I 19 know that some of these cases have specimens for 20 pathology. I know Dr. Iakovlev and Dr. Timms have 21 looked at that. So some of the patients have 22 explants. Some don't. 23 Q. Do you know who has an explant and who 24 does not?</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 90</p> <p>1 A. No. Again, I didn't review the medical 2 records. 3 Q. Doctor, do you think it would have been 4 helpful for you to have reviewed or inspected a 5 plaintiff's explant in this litigation? 6 MR. BOWMAN: Object to form. 7 THE WITNESS: I mean, again, 8 Dr. Iakovlev is providing those patient-specific 9 opinions. My opinions are -- I mean, it would have 10 been helpful, but it's a lot of cases. It's a lot 11 of explants. It's a lot going on. 12 BY MR. HUTCHINSON: 13 Q. Right. But you wish you would have at 14 least had the opportunity to have reviewed an 15 implant -- I mean, I'm sorry -- an explant, 16 correct? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: It would have been 19 helpful, but not realistic. I mean, it's just -- 20 BY MR. HUTCHINSON: 21 Q. Why wouldn't it have been realistic? 22 A. Well, there's -- there's just a lot of 23 plaintiffs. There's a lot of patients. There's a 24 lot of explants and there's other experts that are</p> | <p style="text-align: right;">Page 92</p> <p>1 when it was in her body? 2 MR. BOWMAN: Object to form. 3 THE WITNESS: I didn't specifically 4 look for oxidation in her mesh. What I've been 5 telling the jury is that my opinion is that 6 there's -- there's a significant risk of this 7 happening. It's a -- that's been the body of my 8 opinions and my testimony. But I'm not giving a 9 patient-specific opinion about Ms. Babcock. I -- I 10 didn't look at that. 11 BY MR. HUTCHINSON: 12 Q. Then, Doctor, are you -- did you 13 specifically look for oxidation for any of these 14 women listed on Exhibit 1, the notice of 15 deposition? 16 A. No. My understanding is that 17 Dr. Iakovlev is -- is doing that explant work. And 18 so this is -- this is an effort where there's lots 19 of experts involved. And Dr. Iakovlev is giving 20 those patient-specific opinions. 21 Q. Doctor, is it fair to say that you've 22 never done any analytical testing of explants of 23 PROLENE mesh? 24 A. I mean, I think you asked this before.</p> |
| <p style="text-align: right;">Page 91</p> <p>1 working with those explants. So they have to be 2 managed in a -- in a way that's appropriate. And 3 if Dr. Iakovlev needs explants to do the microscopy 4 then -- for a patient-specific opinion, then he 5 needs to have priority to look at that explant. 6 Q. And, Doctor, have you ever asked to 7 inspect any of the explants available from these 8 women? 9 A. I've not asked in a specific case. 10 Q. Why not? 11 A. Again, there just isn't time. I mean, 12 it's -- it's not a realistic request. 13 Q. Doctor, if you were giving an opinion 14 about a specific product, would you not want to 15 have all the evidence available to you before 16 giving that opinion? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: Again, I wasn't giving a 19 patient-specific opinion. I was giving an opinion 20 about what happens to polypropylene when it's 21 implanted in the body. That's -- so -- 22 BY MR. HUTCHINSON: 23 Q. I understand. But are you going to 24 tell the jury that Marty Babcock's mesh oxidized</p> | <p style="text-align: right;">Page 93</p> <p>1 Not PROLENE, but the AMS mesh. 2 Q. And you've never done any physical 3 property testing of PROLENE explants, have you? 4 A. Not for PROLENE. 5 Q. And not of pristine PROLENE, have you? 6 A. Well, again, the work that I referred 7 to earlier with Dr. Dunn, I believe there were some 8 Ethicon meshes in those measurements of molecular 9 weight, but it's been a long time and we haven't 10 been relying on that. But -- but we did something 11 like that a couple years ago. 12 Q. Doctor, you've never done any tests to 13 confirm oxidation of the mesh contained in any of 14 these women listed on the notice of deposition, 15 correct? 16 A. Again, I -- I thought I answered that, 17 too. Dr. Iakovlev is doing that. I'm not giving 18 those patient-specific opinions. 19 Q. And, Doctor, can you make any 20 prediction about when the mesh, from any of these 21 44 women, would oxidate in vivo? 22 MR. BOWMAN: Object to form. 23 THE WITNESS: Again, I -- my testimony 24 has been that it's -- it's a risk. There's a lot</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 94</p> <p>1 of factors that affect it and in what patient and 2 at what time. It's not -- that's the problem is 3 you -- you -- you can't predict it. I mean, 4 that's -- that's the problem is it's unpredictable. 5 BY MR. HUTCHINSON: 6 Q. In fact, you can't make any type of 7 prediction of when Marty Babcock's mesh oxidized in 8 her body, can you? 9 MR. BOWMAN: Object to form. 10 THE WITNESS: That's not in my opinions 11 in my report. My report is that this is a risk. 12 This -- this happens. And it depends on, you know, 13 it's -- it's a risk. You can't predict when it's 14 going to happen. You can't design around it. 15 That's my opinion. It's not -- I didn't write an 16 opinion specific to Ms. Babcock when it's going to 17 oxidize or did it. I . . . 18 BY MR. HUTCHINSON: 19 Q. And you can't even sit here today 20 telling us whether or not Marty Babcock's mesh 21 oxidized in the body, can you? 22 MR. BOWMAN: Object to form. 23 THE WITNESS: I believe it's oxidizing. 24 That's the chemical reaction. But the implications</p> | <p style="text-align: right;">Page 96</p> <p>1 tells you that that would be -- you would expect it 2 to oxidize and degrade. The -- the timing of that 3 is unpredictable. That's what I've said. I didn't 4 measure it. But scientific evidence -- 5 polypropylene oxidizes. There are cells in the 6 body that make reactive oxygen species, and you 7 would expect it to oxidize in the body based on 8 the -- what we know scientifically. 9 BY MR. HUTCHINSON: 10 Q. I understand that. But I'm -- my 11 question is related to these 44 women. Can you 12 tell us, to a reasonable degree of scientific 13 certainty, whether or not the mesh, in any of these 14 44 women, ever oxidized? 15 MR. BOWMAN: Object to form. This is 16 asked and answered. 17 THE WITNESS: I feel like we're going 18 to go round and round on this. 19 (Simultaneous speaking.) 20 MR. BOWMAN: I'm going to instruct him 21 not to answer. 22 (Reporter interruption for 23 clarification.) 24 MR. BOWMAN: I said if we're going to</p> |
| <p style="text-align: right;">Page 95</p> <p>1 of that are difficult to predict. 2 BY MR. HUTCHINSON: 3 Q. But my question is, sir, are you 4 testifying, to a reasonable degree of scientific 5 certainty, without having reviewed an explant, that 6 Marty Babcock's mesh is oxidizing in her body? 7 MR. BOWMAN: Object to form. 8 THE WITNESS: I mean, I believe that 9 the science tells you it's oxidizing. I did not 10 specifically measure it. 11 BY MR. HUTCHINSON: 12 Q. Thank you. In fact, you didn't 13 specifically measure oxidation of any of the women 14 listed in Exhibit Number 1, correct? 15 A. I've already answered that. No. 16 Q. Okay. 17 A. Yeah, I didn't do that. 18 Q. And you can't tell us whether or not 19 the mesh of any of the women listed in Exhibit 1 20 oxidized in their body, can you? 21 MR. BOWMAN: Object to the form. Asked 22 and answered. 23 THE WITNESS: I believe I've asked -- 24 I've answered this. I mean, it's -- the science</p> | <p style="text-align: right;">Page 97</p> <p>1 keep asking the same question, I'm going to start 2 instructing him not to answer. 3 BY MR. HUTCHINSON: 4 Q. I need a clean answer, then I'll move 5 on. 6 MR. BOWMAN: Objection. 7 THE WITNESS: I'm giving you my clean 8 answer. I've said this in trials. I've said this 9 in depositions. You know the record of my 10 testimony. It hasn't changed. 11 The scientific principles states that 12 this chemical reaction is going to occur. It's 13 going to oxidize. The clinical implications of 14 that are unknown. I did not specifically look at 15 oxidation in these meshes. My testimony has been 16 that these reactions are occurring. And the 17 clinical implication of that in a specific patient 18 is unknown. It's unpredictable. That's been my 19 testimony. I -- 20 BY MR. HUTCHINSON: 21 Q. And you can't tell us when it's 22 occurring, can you, in any of these 44 women? 23 A. I think that's what unpredictable means 24 is you don't -- you don't know when it's -- when it</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 98</p> <p>1 could happen, when it -- when it happens. You 2 don't -- you don't know when that's going to occur. 3 Q. Doctor, can you tell us the name of a 4 patient who has had their mesh removed specifically 5 because of oxidations? 6 A. I mean, in the papers, the patient 7 names aren't provided. It's a violation of 8 confidentiality rules. I mean, in the -- 9 Q. Okay. Then let's not -- 10 A. In a specific case. 11 Q. Okay. Then let's not look -- 12 A. I mean, all these case -- 13 Q. Let's look at the -- let's not look at 14 the papers or the literature. 15 A. I mean, I don't want to get into 16 patient names. That's kind of -- there's all these 17 cases, and this is a specific case. I mean, we've 18 looked at the plaintiffs in this specific case. I 19 don't -- I'm not comfortable discussing specific 20 patients from other litigations. 21 Q. I understand. And I'm not asking you 22 to discuss any patients from any literature or any 23 other litigation. What I'm asking about is the 24 Ethicon litigation.</p> | <p style="text-align: right;">Page 100</p> <p>1 I said, I haven't reviewed their records. I don't 2 know why their mesh was removed. 3 Q. Okay. And you -- you don't -- you 4 can't tell us the name of one patient, of any of 5 these nine products, who had their mesh removed 6 specifically because of oxidation? 7 A. I just answered that. 8 Q. No. You told me it was a strange 9 question. 10 A. Well, it is a strange question. I 11 stick by that. 12 But meshes are removed because of 13 complications, like pain, erosion, and extrusion 14 that a clinician can see. So -- I -- I just don't 15 want to be trapped in some kind of answer, yes or 16 no, to a question like that. They -- 17 Q. Well, Doctor, I'm entitled to flesh out 18 your opinions. And my question is can you tell us, 19 sitting here today, the name of a person, who 20 received any one of these nine products, who had 21 their mesh specifically removed because of 22 oxidation? 23 MR. BOWMAN: You can answer yes or no. 24 THE WITNESS: No, none of these</p> |
| <p style="text-align: right;">Page 99</p> <p>1 Can you tell us the name of a patient, 2 who received any one of the nine products, who had 3 their mesh specifically removed because of 4 oxidation? 5 A. Why would you remove a mesh for 6 oxidation? You remove it for another complication. 7 I mean, it's not -- oxidation leads to 8 embrittlement and degradation. So -- I mean, 9 they're -- they're removed because they become 10 embrittled. They extrude. They cause pain. Not 11 because -- I mean, there's not -- you wouldn't -- 12 I'm confused. I'm sorry. Go ahead. 13 MR. HUTCHINSON: Move to strike as 14 nonresponsive. 15 BY MR. HUTCHINSON: 16 Q. Doctor, I'm asking for a name of 17 somebody who received any one of these nine 18 products who had their mesh specifically removed 19 because of oxidation. Can you tell us a name? Yes 20 or no? And then I'll move on. 21 A. This is a strange question. You 22 wouldn't remove a mesh for oxidation. It's a very 23 early event. I mean, I don't know that any of 24 these patients had it removed for oxidation. Like</p> | <p style="text-align: right;">Page 101</p> <p>1 patients -- 2 MR. BOWMAN: If you can. 3 THE WITNESS: To my knowledge, none of 4 them -- I don't -- I don't know that any of them -- 5 BY MR. HUTCHINSON: 6 Q. I'm sorry. "To my knowledge none of 7 them" what? 8 A. I don't know -- I said I don't know why 9 the mesh was removed in these patients. So I 10 wouldn't know if it was removed to oxidation 11 [verbatim]. I don't know that any of them had it 12 removed for -- because of oxidation. 13 Q. Okay. 14 A. I don't know that. 15 Q. And you can't tell us the name of one 16 person who had their mesh removed because of 17 oxidation, can you? 18 A. Why are you -- 19 MR. BOWMAN: Object to form. 20 THE WITNESS: I'm really -- I'm getting 21 a little frustrated. Can we answer this and take a 22 break? I don't want to get angry. 23 BY MR. HUTCHINSON: 24 Q. That's fine. Just answer it, and then</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 102</p> <p>1 we can take a break.</p> <p>2 A. The name -- the 44 names on this</p> <p>3 list --</p> <p>4 Q. My question to you is can you tell us</p> <p>5 the name, sir, of one patient who received any one</p> <p>6 of the nine products who had their mesh</p> <p>7 specifically removed because of oxidation?</p> <p>8 A. I've already answered that. I don't</p> <p>9 know of a patient that had it removed because of</p> <p>10 oxidation of these 44 patients.</p> <p>11 Q. Okay. Or of any patients, not</p> <p>12 necessarily the 44.</p> <p>13 A. I'm going with these 44 patients</p> <p>14 because it's this litigation. I don't want to</p> <p>15 answer questions about other litigation.</p> <p>16 Q. Okay.</p> <p>17 A. I thought I made that clear. I'm</p> <p>18 talking about these 44 patients.</p> <p>19 Q. Okay. Thank you.</p> <p>20 A. Can we take a break? I don't want to</p> <p>21 get agitated.</p> <p>22 MR. HUTCHINSON: That's fine.</p> <p>23 (Brief recess.)</p> <p>24 BY MR. HUTCHINSON:</p> | <p style="text-align: right;">Page 104</p> <p>1 question.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. All right. Doctor, have you ever</p> <p>4 instructed your students at Vanderbilt to use</p> <p>5 scientific data in reaching a conclusion?</p> <p>6 MR. BOWMAN: Object to form.</p> <p>7 THE WITNESS: Again, we do experiments,</p> <p>8 make measurements and test hypotheses.</p> <p>9 BY MR. HUTCHINSON:</p> <p>10 Q. All right. And, Doctor, let's talk</p> <p>11 about these nine specific products that you're here</p> <p>12 to give testimony about.</p> <p>13 Are you aware of any data that confirms</p> <p>14 these nine specific products degraded to the extent</p> <p>15 it compromised the functionality of the product?</p> <p>16 MR. BOWMAN: Object to form.</p> <p>17 THE WITNESS: Again, you've asked this</p> <p>18 many times. I've not looked at physical changes in</p> <p>19 these specific products, these patients. I've not</p> <p>20 looked at that. I didn't test the explants.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. I understand that. But my question is</p> <p>23 a little bit more general, is -- and it relates to</p> <p>24 these nine specific products, okay? Are you aware</p> |
| <p style="text-align: right;">Page 103</p> <p>1 Q. Dr. Guelcher, do you have any evidence</p> <p>2 to confirm that any of the -- these women had</p> <p>3 molecular weight loss of their explants?</p> <p>4 A. You know, I didn't look at molecular</p> <p>5 weight in -- as I said before, I didn't look at</p> <p>6 their explants. I didn't look at their patient</p> <p>7 records.</p> <p>8 Q. Doctor, do you have any evidence to</p> <p>9 confirm that any of these women -- and, again, I'm</p> <p>10 talking about the women that you're here to give</p> <p>11 testimony about today -- had explants that had a</p> <p>12 change in physical properties?</p> <p>13 A. No. I didn't look at patient explants,</p> <p>14 so I don't know the change in physical properties.</p> <p>15 Q. And, Doctor, do you have any evidence</p> <p>16 to confirm that these women's explants lost any</p> <p>17 antioxidants?</p> <p>18 A. No. Again, that wasn't measured,</p> <p>19 whether they lost antioxidants.</p> <p>20 Q. And, Doctor, using solid scientific</p> <p>21 data is good science, isn't it?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: That's a very vague --</p> <p>24 I'm not -- I'm not sure what you mean by that</p> | <p style="text-align: right;">Page 105</p> <p>1 of any data that confirms these nine products will</p> <p>2 degrade to the extent their intended function is</p> <p>3 compromised during a woman's lifetime?</p> <p>4 MR. BOWMAN: Object to the form.</p> <p>5 THE WITNESS: Again, you asked this</p> <p>6 before and I said, no, for these products that's</p> <p>7 not been directly measured.</p> <p>8 BY MR. HUTCHINSON:</p> <p>9 Q. And, Doctor, do you know -- we talked</p> <p>10 about -- well, strike that.</p> <p>11 Do you know what the mechanism of</p> <p>12 action of tissue negatively reacting to any of</p> <p>13 these nine products is?</p> <p>14 MR. BOWMAN: Object to form.</p> <p>15 THE WITNESS: Can you repeat that?</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. Right. Doctor, do you believe that the</p> <p>18 tissue in women negatively reacts to any of these</p> <p>19 nine products?</p> <p>20 A. The --</p> <p>21 Q. Or are you qualified to give that</p> <p>22 opinion?</p> <p>23 A. Well, I believe I'm -- that's what my</p> <p>24 report is about. That's what these papers are</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 106</p> <p>1 about, is that the -- the macrophage is to treat 2 reactive oxygen that degrades the polypropylene. 3 Has that been tested for these nine specific 4 products? Well, you asked about this earlier. And 5 I -- I said I don't know of any study looking at 6 these nine specific projects, but that's -- 7 Q. You mean products, not projects? 8 A. Products. But that's -- but the nature 9 of the chemistry in the inflammatory reaction and 10 the nature of the material tells us that these 11 things will happen, but -- 12 Q. All right. Well, Doctor, what is -- 13 A. -- it's not been specifically measured, 14 for these products. 15 Q. What is the mechanism of action of how 16 tissue negatively reacts to any of these nine 17 products? 18 MR. BOWMAN: Object to form. 19 THE WITNESS: I mean -- but -- but 20 my -- my struggle is your question is very vague. 21 I mean, there's a number of tissue reactions. 22 There can be a fibrotic response, which is 23 fibroblasts migrating in and laying down a scar 24 plate, by depositing extra cellular matrix</p> | <p style="text-align: right;">Page 108</p> <p>1 properties, again, is -- is broad. I mean, it's -- 2 BY MR. HUTCHINSON: 3 Q. Of the -- of the material. 4 A. It -- 5 Q. Oxidation -- you talked about oxidation 6 leads to reduced molecular weight. Oxidation also 7 leads to reduced physical properties, correct? 8 A. Like what physical properties are you 9 referring to? I'd like you to be more specific. I 10 mean, it's -- it's reducing the molecular weight, 11 which leads to embrittlement. That's the science 12 of polypropylene oxidation. It's in the report. 13 I'm not sure what you mean by other 14 physical properties. It would help me if you could 15 be more specific. 16 Q. Well, oxidation, Doctor, causes a 17 reduction in tensile strength, doesn't it? 18 A. Reduction -- that's a mechanical 19 property, right? So. . . 20 Q. Well, strike that. 21 So let me be clear, and we can just 22 move on. 23 A. Okay. I'm just struggling to 24 understand your question.</p> |
| <p style="text-align: right;">Page 107</p> <p>1 resulting in a scar plate. I should be more 2 precise. 3 There's the macrophages and other 4 inflammatory cells, foreign body giant cells, that 5 migrate into the mesh, adhere to the mesh, secrete 6 reactive oxygen species, including hydroxyl 7 radicles, that oxidize the polypropylene. That -- 8 that -- that's in my report. That's the -- that's 9 the tissue response. The primary components are 10 the fibroblasts and -- and with the collagen matrix 11 deposition and the -- and the macrophages. 12 BY MR. HUTCHINSON: 13 Q. Doctor, can you tell us from a 14 physiological standpoint how oxidation causes pain 15 in a woman? 16 A. Again, it's in my report. Oxidation 17 leads to reduction of molecular weight, 18 embrittlement, and that can lead to cracking, which 19 can lead to erosions and pain. It's hard plastic 20 in the pelvic floor. That's going to cause pain. 21 Q. And oxidation also leads to reduction 22 in physical properties, correct? 23 MR. BOWMAN: Objection to form. 24 THE WITNESS: What -- physical</p> | <p style="text-align: right;">Page 109</p> <p>1 Q. That's fine. Oxidation -- stay with 2 me. Do you need to take another break? 3 A. No. I'm fine. 4 Q. All right. Oxidation leads to a 5 reduction in mechanical properties of the mesh, 6 correct? 7 A. Yeah. It leads to changes. It leads 8 to embrittlement, which would be the material 9 becomes brittle rather than a ductile polymer. 10 Q. And a loss of molecular weight leads to 11 reduced tensile strength, doesn't it? 12 A. Yeah, I mean, it can. If you have a 13 reduction in molecular weight, it -- it depends 14 on -- reduction in molecular weight can lead to 15 reduced strength. 16 Q. Okay. And we're talking about strength 17 is how -- is how tough a polymer is; is that right? 18 A. Well, I wouldn't say -- tough is an 19 area under the stress versus strain curve, but 20 strength is the force or the -- you know, the -- 21 the stress, the force per unit area required to 22 break the fiber or the mesh. 23 Q. Well, loss of molecular weight leads to 24 a decrease in toughness under the stress-strain</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 110</p> <p>1 curve, doesn't it?</p> <p>2 A. I mean, it can. It's -- it's -- if</p> <p>3 it's -- if it becomes embrittled, it's going to</p> <p>4 fail at a lower elongation or strain, and that</p> <p>5 would lead to reduction in toughness.</p> <p>6 Q. In fact, that's what you would expect</p> <p>7 as a polymer scientist. If a polymer becomes</p> <p>8 embrittled there will be a decrease in toughness</p> <p>9 under the stress-strain curve, correct?</p> <p>10 A. It -- generally speaking, it would, but</p> <p>11 the problem is this is happening at the surface of</p> <p>12 the fiber. So it's difficult to measure it. It's</p> <p>13 not uniformly distributed across the diameter of</p> <p>14 the fiber. So you may not be able to measure a</p> <p>15 difference in strength even if the fiber is</p> <p>16 cracked. It -- it just depends on other things.</p> <p>17 Because strength is a bulk volume average property</p> <p>18 versus what's happening at the surface.</p> <p>19 Q. Sir, would a crack in a polymer</p> <p>20 increase or decrease its mechanical properties?</p> <p>21 A. Depends on how deep it is. If it's --</p> <p>22 if it's -- if it's a penetrating -- you can have</p> <p>23 crack propagation which can lead to failure of the</p> <p>24 fiber.</p> | <p style="text-align: right;">Page 112</p> <p>1 A. Well, if the strain and stress to</p> <p>2 break -- if the tensile strength or the elongation</p> <p>3 at break --</p> <p>4 (Reporter interruption for</p> <p>5 clarification.)</p> <p>6 THE WITNESS: Elongation at break --</p> <p>7 sorry -- is reduced, then the toughness would be</p> <p>8 reduced if it's the area under the stress-strain</p> <p>9 curve.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. In fact, Doctor, you're familiar with</p> <p>12 the area under the stress-strain curve, aren't you?</p> <p>13 A. Familiar with it?</p> <p>14 Q. Yeah. You're familiar with the</p> <p>15 concept --</p> <p>16 A. Yes.</p> <p>17 Q. -- toughness as defined --</p> <p>18 A. Yeah, I've published on that. Yes.</p> <p>19 Q. Yes. Okay. And that's something you</p> <p>20 teach your students about; is that right?</p> <p>21 A. I've taught that before.</p> <p>22 Q. Doctor, when we get -- let's go -- go</p> <p>23 back to antioxidants for a minute. I think you and</p> <p>24 I can agree that the formulated product PROLENE has</p> |
| <p style="text-align: right;">Page 111</p> <p>1 Q. Doctor, would you expect a crack in a</p> <p>2 polymer to ever increase the mechanical properties</p> <p>3 of that polymer?</p> <p>4 A. Seems unlikely.</p> <p>5 Q. Thank you.</p> <p>6 And, Doctor, if there was a crack in a</p> <p>7 PROLENE fiber, you would expect that PROLENE fiber</p> <p>8 to have reduced mechanical properties, wouldn't</p> <p>9 you, sir?</p> <p>10 A. As I said, it depends on the depths of</p> <p>11 the crack. It depends on -- I mean, the</p> <p>12 embrittlement -- these reactions all occur at the</p> <p>13 surface of the fiber, and they move inwards. So</p> <p>14 it -- it just depends. I mean, if the crack were</p> <p>15 deep enough, it would affect the mechanical</p> <p>16 properties. But it's not always going to be --</p> <p>17 it's difficult to say every single time. I mean,</p> <p>18 cracks generally reduce mechanical properties, but</p> <p>19 it -- it's going to depend on the depth of the</p> <p>20 crack and crack propagation and all that.</p> <p>21 Q. I understand. And -- and -- and,</p> <p>22 Doctor, you would expect a crack in a PROLENE fiber</p> <p>23 to decrease the toughness of that PROLENE fiber,</p> <p>24 wouldn't you?</p> | <p style="text-align: right;">Page 113</p> <p>1 antioxidants in it, correct?</p> <p>2 A. It does. DLTDP -- and I don't remember</p> <p>3 the name of the other one. There are two</p> <p>4 different -- one is a radical scavenger. The</p> <p>5 other, I think, is a sulfa compound, thio compound.</p> <p>6 I can't -- thioester. I can't remember the exact</p> <p>7 chemical formula.</p> <p>8 (Whereupon Exhibit 5 was marked as an</p> <p>9 exhibit.)</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, I'll hand you what we'll mark</p> <p>12 as Exhibit 5 to your deposition.</p> <p>13 A. Okay.</p> <p>14 Q. Can you draw out the chemical structure</p> <p>15 of DLTDP as used in PROLENE in any of these nine</p> <p>16 products?</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: I don't remember the</p> <p>19 chemical structure of the -- of the antioxidant.</p> <p>20 BY MR. HUTCHINSON:</p> <p>21 Q. Doctor, can you draw out the chemical</p> <p>22 structure of Sanotox R, on that sheet of paper I've</p> <p>23 handed you marked as Exhibit 5, as used in any of</p> <p>24 these nine products?</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 114</p> <p>1 A. I don't remember the chemical structure 2 that I could write it down. 3 Q. You could? 4 A. No. I don't remember what it exactly 5 is. 6 Q. You can't draw the chemical structures 7 on Exhibit 5 of DLTDP or Sanotox R, can you? 8 MR. BOWMAN: Object to form. 9 THE WITNESS: I mean, I haven't 10 memorized their chemical structures. I know what 11 they do and what they are, but I haven't memorized 12 their chemical structures. I don't typically do 13 that in my. . . 14 BY MR. HUTCHINSON: 15 Q. Doctor, can you show me chemically how 16 they perform in oxidation -- I'm sorry. 17 Can you show me chemically how they 18 perform as antioxidants, on that piece of paper as 19 Exhibit 5? 20 MR. BOWMAN: Object to form. 21 THE WITNESS: Again, that's a complex 22 reaction mechanism. I haven't memorized it. It's 23 in a number of books. But my understanding is it's 24 basically, you know, radical scavenger. I mean,</p> | <p style="text-align: right;">Page 116</p> <p>1 blend. It's a composite. It's polypropylene with 2 these other additives in it. So I'm not -- you 3 want me to draw the -- I mean, I'm not sure what 4 you want me to do. 5 BY MR. HUTCHINSON: 6 Q. I want you to draw the chemical 7 structure for PROLENE. Can you do that on Exhibit 8 5? 9 MR. BOWMAN: Object to form. 10 THE WITNESS: You can't draw the 11 chemical structure of PROLENE because it's 12 polypropylene with all these other -- other 13 additives in it. So it's not a -- it's not a 14 specific molecule. It's a formulation. It's a 15 blend. It's not -- 16 BY MR. HUTCHINSON: 17 Q. Sir, do you know what the chemical 18 structure for polypropylene looks like? 19 A. Yeah. I mean, it's in my report. I 20 mean, it's -- 21 Q. I mean, Doctor, where, on that chemical 22 chain, are the additives of DLTDP and Sanotox R 23 added? Can you tell us that? 24 MR. BOWMAN: Object to form.</p> |
| <p style="text-align: right;">Page 115</p> <p>1 scavenging free radicles that -- that are produced 2 in this oxidation reaction. Whether they come 3 from -- I'll leave it at that. 4 BY MR. HUTCHINSON: 5 Q. Doctor, on Exhibit 5, can you draw the 6 chemical structure for PROLENE as used in any of 7 these nine products? 8 MR. BOWMAN: Object to form as to 9 "draw." 10 THE WITNESS: Again, it's a difficult 11 question. I mean, PROLENE is polypropylene with 12 some additives in it. So it's -- I don't remember 13 the exact compositions of the additives. It's in 14 the, you know, half percent to percent range. It's 15 pretty low. 16 BY MR. HUTCHINSON: 17 Q. Right. And my question, Doctor, is not 18 whether you remember, but can you draw the chemical 19 structure for PROLENE as used in any of these nine 20 products on the piece of paper I've marked as 21 Exhibit 5 to your deposition? 22 MR. BOWMAN: Object to form. 23 THE WITNESS: But you can't draw the 24 composition of PROLENE. It's a -- it's a -- it's a</p> | <p style="text-align: right;">Page 117</p> <p>1 THE WITNESS: I don't -- I don't think 2 that they're added to the chain. They're blended 3 in with the polymer. I don't -- I don't think 4 they're necessarily reacting with it. 5 BY MR. HUTCHINSON: 6 Q. Doctor, do you know what step in the 7 manufacturing process DLTDP or Sanotox R is added? 8 A. In the manufacturing process of 9 PROLENE? 10 Q. Yes, sir. 11 A. Could you repeat the question? I'm 12 not, again, sure what you're asking. 13 Q. Do you know what step in the 14 manufacturing process where DLTDP and Sanotox R are 15 added? 16 MR. BOWMAN: Object to form. 17 THE WITNESS: I mean, these are 18 added -- it's in my report. They're -- they're 19 added to protect PROLENE. 20 BY MR. HUTCHINSON: 21 Q. Right. We're going to get to the 22 reason in a minute. But I'm asking you what step 23 in the manufacturing process -- 24 A. Well, it's --</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 118</p> <p>1 Q. -- these additives are added to 2 polypropylene? 3 A. Well, I was getting there. But -- so 4 the PROLENE is manufactured as pellets that are 5 then extruded into a monofilament, and my 6 understanding is it's added to those pellets prior 7 to the extrusion step. That some of the flow 8 additives can help with flow of the melt polymer 9 during extrusion, and then the antioxidants, one of 10 them at least, is protecting it from high 11 temperature oxidation during extrusion. So that's 12 my understanding of when those additives are added. 13 Q. Doctor, have you ever done any type of 14 analysis to determine whether or not the 15 antioxidants, contained in any of these nine 16 products, have been depleted? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: I've not done that, but 19 Ethicon had done that. 20 BY MR. HUTCHINSON: 21 Q. And you had the equipment at your lab 22 at Vanderbilt to do that testing, didn't you, sir? 23 A. I could do that at Vanderbilt, but 24 it -- it -- it takes funding to do that. I don't</p> | <p style="text-align: right;">Page 120</p> <p>1 sit here today -- or strike that. 2 Do you have any scientific data that 3 shows antioxidants from any of these nine products 4 are toxic to the adjacent tissue surrounding the 5 product? 6 A. I've not opined that they're toxic to 7 the tissue. My opinions is limited to that they 8 are being depleted during this oxidation. That was 9 my opinion in the report. 10 Q. And, Doctor, can you tell us at what 11 point in time these antioxidants are depleted? 12 A. Again, it's unpredictable. It's -- 13 it's -- the oxidation reactions happen and when the 14 antioxidants are depleted, when the degradation 15 starts, all of these events are -- are 16 unpredictable. That's why -- that's part of my 17 opinion, that that's a problem, that that needs to 18 be controlled. 19 Q. Doctor, we were talking about physical 20 properties of mesh in -- just a minute ago. 21 Have you ever tested the physical 22 properties of the mesh in any of these nine 23 products, such as durability? 24 A. What do you mean by "durability"?</p> |
| <p style="text-align: right;">Page 119</p> <p>1 have any research grants on that. It's not what I 2 do. I mean, I -- I can't -- I -- I -- I don't have 3 funding to answer that question, so I haven't done 4 that. 5 Q. And, Doctor, can you tell us what the 6 rate is for the antioxidants allegedly depleting 7 from each of these nine products? 8 A. Again, I thought I answered that. I 9 haven't measured the degradation of the 10 antioxidants in the -- in the PROLENE other than 11 those Ethicon studies that reported loss of 12 antioxidants from oxidized polypropylene. That was 13 the study that I was relying on, my opinions, one 14 of the studies. 15 Q. And, Doctor, it's fair to say that you 16 have never tested the effect antioxidants have, in 17 vivo, on Ethicon's nine products that we're here 18 about today on? 19 MR. BOWMAN: Object to form. 20 THE WITNESS: I've not looked at the 21 antioxidant depletion in these products, in vitro 22 or in vivo. 23 BY MR. HUTCHINSON: 24 Q. Doctor, do you have any evidence, as we</p> | <p style="text-align: right;">Page 121</p> <p>1 Q. The physical property of durability. 2 A. I mean -- 3 MR. BOWMAN: Object to form. 4 THE WITNESS: How are you defining 5 that? 6 BY MR. HUTCHINSON: 7 Q. Sir, have you ever -- have you ever 8 heard the word "durability" before as a polymer 9 scientist? 10 A. Yeah, I've heard -- I've heard the 11 word, but it would help me if you would -- 12 Q. Well, my question is -- 13 A. -- tell me the definition. 14 Q. -- using your definition, have you ever 15 tested the durability of the mesh of any of these 16 nine products? 17 A. I mean, I -- 18 MR. BOWMAN: And I just want to stress 19 right here this is asked and answered. He already 20 testified that he hasn't tested any exemplar meshes 21 or anything about this -- that was before the last 22 break. I just want to keep moving. We've only got 23 about an hour left. I mean, I don't want to spend 24 20 minutes on this if we can help it. But that's</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 122</p> <p>1 my opinion.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, durability, tensile strength,</p> <p>4 elongation, toughness, Young's modulus, have you</p> <p>5 ever studied those physical properties of the mesh</p> <p>6 in any of these nine products?</p> <p>7 A. No. As I've said, I've not tested</p> <p>8 these meshes, these nine meshes, these nine</p> <p>9 products, other than the work we did with the TVT</p> <p>10 on the molecular weight analysis and the IR with</p> <p>11 Dr. Dunn. That's what we did.</p> <p>12 Q. But, Doctor, have you done any tests,</p> <p>13 tests, on any of these nine products that can be</p> <p>14 repeated and confirmed?</p> <p>15 A. Well, I just answered your question, I</p> <p>16 thought. We did FTIR, and we did the molecular</p> <p>17 weight analysis, I believe, on the TVT a couple</p> <p>18 years ago.</p> <p>19 Q. And you're talking about --</p> <p>20 A. It was one of Dr. Dunn's earlier</p> <p>21 reports.</p> <p>22 Q. Right. But you're talking about the</p> <p>23 FTIR analysis --</p> <p>24 A. No, I'm not talking about that. I'm</p> | <p style="text-align: right;">Page 124</p> <p>1 A. Yes.</p> <p>2 Q. And forgive me -- and chain scission</p> <p>3 also produces carbonyl bands, correct?</p> <p>4 A. It's in the report, that -- that --</p> <p>5 hydrox- -- hydroperoxide and carbonyl groups result</p> <p>6 in the chain --</p> <p>7 (Reporter interruption for</p> <p>8 clarification.)</p> <p>9 THE WITNESS: Yeah. So it's in the</p> <p>10 report that -- that -- I'll just keep it simple.</p> <p>11 The carbonyl groups are part of the oxidation</p> <p>12 process.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. Right. But you've never seen a</p> <p>15 carbonyl band on an FTIR from any of the nine</p> <p>16 products after it's been implanted in vivo, have</p> <p>17 you?</p> <p>18 A. After it's been implanted in vivo, I've</p> <p>19 not -- as I said, I've not tested explant on those</p> <p>20 nine products. So I have not done that.</p> <p>21 Q. Doctor, you'll -- you -- when you were</p> <p>22 preparing for this litigation, you understood that</p> <p>23 PROLENE is what sutures are made out of, correct?</p> <p>24 A. Some sutures. I mean, PROLENE is a --</p> |
| <p style="text-align: right;">Page 123</p> <p>1 talking about exemplars. I'm talking about --</p> <p>2 well, okay. So this study, too, we -- we did the</p> <p>3 FTIR and the SEM and --</p> <p>4 Q. But you're deferring to Dr. Dunn on the</p> <p>5 FTIR and SEM for that -- for the study marked as</p> <p>6 Exhibit 3, aren't you?</p> <p>7 A. For the details of the experiments?</p> <p>8 Q. Correct.</p> <p>9 A. Yeah. We talked about that already.</p> <p>10 Multiple times.</p> <p>11 MR. BOWMAN: If can I just clear</p> <p>12 something up for you.</p> <p>13 MR. HUTCHINSON: (Indicating.)</p> <p>14 MR. BOWMAN: There was some molecular</p> <p>15 weight testing done for an AMS report that was like</p> <p>16 2013 or 2014. And that got into -- they got into</p> <p>17 that in the very first deposition that he had</p> <p>18 taken. I can produce it to you, whatever you like,</p> <p>19 but all that stuff's already been turned over and</p> <p>20 discussed is my understanding.</p> <p>21 MR. HUTCHINSON: Okay.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. And I may have asked this already. But</p> <p>24 chain scission lowers molecular weight, doesn't it?</p> | <p style="text-align: right;">Page 125</p> <p>1 is the trademark name that Ethicon has given to its</p> <p>2 polypropylene --</p> <p>3 Q. Right. And do you know how long --</p> <p>4 A. -- formulation.</p> <p>5 Q. And do you know how long Ethicon</p> <p>6 sutures have been on the market?</p> <p>7 A. Since the '60s.</p> <p>8 Q. Do you have any criticisms of Ethicon</p> <p>9 sutures?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 THE WITNESS: Criticisms? That's -- I</p> <p>12 mean, this report is about mesh. It's not about</p> <p>13 sutures.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Okay. But your report is also about</p> <p>16 PROLENE, correct?</p> <p>17 A. Yes. There's PROLENE --</p> <p>18 Q. And sutures are made out of PROLENE,</p> <p>19 aren't they?</p> <p>20 A. They can be. Some sutures are made out</p> <p>21 of PROLENE.</p> <p>22 Q. And do you have any criticisms of</p> <p>23 sutures made out of PROLENE, as you sit here today?</p> <p>24 MR. BOWMAN: Object to form.</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 126</p> <p>1 THE WITNESS: I mean, PROLENE sutures 2 are also made of polypropylene. I would believe 3 they will oxidize and degrade as well. So I think 4 that tells us something about what the mesh will 5 do. But I'm not opining about the effects of 6 sutures and the failure of sutures or -- I'm -- 7 I'm -- the report's about pelvic mesh -- 8 BY MR. HUTCHINSON: 9 Q. I understand that. 10 A. -- made of PROLENE. 11 Q. And you're -- 12 A. I'm not clear what you're asking me. 13 I'm sorry. 14 Q. You're opining about the failure of 15 PROLENE mesh, aren't you? 16 A. Yeah. I mean, I -- yes. 17 Q. All right. Do you -- do you have 18 any -- do you have any criticisms of Ethicon's 19 PROLENE sutures, is my question? 20 A. I think I'm hung up on the word 21 "criticisms." Could you -- 22 Q. Well, Doctor, are you -- 23 A. -- could you be a little more -- 24 Q. I cannot.</p> | <p style="text-align: right;">Page 128</p> <p>1 Q. I understand. I understand that, 2 Doctor. 3 A. I'm really struggling here. 4 Q. But is your opinion -- is it your 5 opinion that every person who has ever had a 6 PROLENE suture has oxidized material in their body? 7 MR. BOWMAN: Object to form. 8 THE WITNESS: I believe that PROLENE is 9 made from polypropylene. It will oxidize in the 10 body. The chemistry, the biology of the 11 inflammatory response tells us these reactions are 12 going on. It's the clinical implications of those 13 reactions that are different. And I'm not speaking 14 about that with regard to sutures. It's about with 15 regard to the mesh. 16 BY MR. HUTCHINSON: 17 Q. I understand that, Doctor. But my 18 question is, is it your opinion that every person 19 who has a PROLENE suture has oxidized material in 20 their body? 21 MR. BOWMAN: Object to form. Asked and 22 answered. 23 THE WITNESS: I believe that I answered 24 it. The material --</p> |
| <p style="text-align: right;">Page 127</p> <p>1 A. Okay. 2 Q. All right. I cannot. 3 Do you have any criticisms -- that word 4 speaks for itself -- of Ethicon's PROLENE sutures? 5 A. But "criticisms" is a broad word. I -- 6 I believe that PROLENE sutures oxidize and degrade 7 just like the mesh but -- 8 Q. Have you -- well, what -- 9 A. Can I finish my answer, please? 10 Q. Yes. 11 A. I'm hoping my answer will make it go 12 away. But -- the -- it's implanted in a different 13 part of the body. It's -- it's a suture. It's not 14 a wo- -- you know, a multi -- it's not a -- it's 15 not a mesh. It's a suture. And so the 16 inflammatory response could be different. Location 17 in the body is different. The -- the chemical 18 reactions are going to be the same. 19 Q. Okay. 20 A. But the clinical implications are 21 different. And I'm not opining about the clinical 22 implications of oxidation and degradation on 23 PROLENE sutures used -- single fiber monofilaments 24 used as sutures. Is that --</p> | <p style="text-align: right;">Page 129</p> <p>1 BY MR. HUTCHINSON: 2 Q. Respectfully, you haven't. 3 A. I have. 4 Q. My question is about PROLENE sutures. 5 MR. BOWMAN: He did -- he did just 6 answer that question. 7 THE WITNESS: I just answered that. 8 PROLENE sutures are made out of polypropylene, and 9 they will be subject to the same oxidation 10 reactions as -- how much oxidized compared to mesh, 11 I don't know. I'm not talking about that. But 12 it's implanted at a different point in the body. 13 It's a single fiber instead of a woven mesh. But 14 it's -- because it's polypropylene, I believe it 15 still will oxidize. It's just the extent of those 16 reactions may be very different because the 17 inflammatory response may be different. I -- 18 BY MR. HUTCHINSON: 19 Q. Have you investigated why there's been 20 a long-term effective use of PROLENE sutures in the 21 body? 22 MR. BOWMAN: Object to form. 23 THE WITNESS: Can you repeat it, 24 please. I'm -- could you repeat the question?</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 130</p> <p>1 BY MR. HUTCHINSON:</p> <p>2 Q. Have you investigated why there's been</p> <p>3 a long-term effective use of PROLENE sutures in the</p> <p>4 body?</p> <p>5 MR. BOWMAN: Object to form.</p> <p>6 THE WITNESS: I don't know how to</p> <p>7 answer that. I've looked at PROLENE sutures.</p> <p>8 There are papers that I've cited. There's Ethicon</p> <p>9 studies about PROLENE sutures that I've looked at.</p> <p>10 And I believe those studies point to evidence of</p> <p>11 oxidation and degradation like I've been</p> <p>12 testifying.</p> <p>13 But the -- the effects of the oxidation</p> <p>14 of a PROLENE suture are going to be different than</p> <p>15 for a PROLENE mesh. It's implanted in a different</p> <p>16 part of the body. It's a different type of device.</p> <p>17 So I don't think you can necessarily infer that the</p> <p>18 safety record with PROLENE sutures translates to</p> <p>19 the mesh.</p> <p>20 (Whereupon Exhibit 6 was marked as an</p> <p>21 exhibit.)</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Handing you what we'll mark as Exhibit</p> <p>24 6 to your deposition. And by the way, before we</p> | <p style="text-align: right;">Page 132</p> <p>1 implanted in their body has oxidized material in</p> <p>2 their body?</p> <p>3 A. Again, I would say how I answered that</p> <p>4 before, that these reactions are ongoing. It's</p> <p>5 reasonable to expect that that material would be</p> <p>6 oxidized. It's just the extent and the clinical</p> <p>7 implications of that are very different because</p> <p>8 it's in a different part of the body.</p> <p>9 Q. Okay. So if I -- I'm just trying to</p> <p>10 understand your answer. But it's your testimony</p> <p>11 that every person that has a PROLENE hernia mesh</p> <p>12 has oxidized material in their body; it's just to</p> <p>13 what extent; is that a fair summary?</p> <p>14 A. To what extent? I would -- I would say</p> <p>15 that --</p> <p>16 Q. No. My -- I'm asking is that a fair</p> <p>17 summary of your testimony?</p> <p>18 A. Could you say it again?</p> <p>19 Q. I did it so good the first time.</p> <p>20 A. Perhaps. But I want to be very clear</p> <p>21 about what I'm saying.</p> <p>22 Q. Let's be clear. Is it your testimony</p> <p>23 that every person who has a PROLENE hernia mesh has</p> <p>24 oxidized material in their body; it's just a matter</p> |
| <p style="text-align: right;">Page 131</p> <p>1 move on, Exhibit 5 remains blank, does it not?</p> <p>2 A. I didn't write anything on Exhibit 5.</p> <p>3 Q. This is the -- Exhibit 6 is the Imel</p> <p>4 article that you cite --</p> <p>5 A. Okay.</p> <p>6 Q. -- in your report. You've seen this,</p> <p>7 Doctor, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the first paragraph, first sentence</p> <p>10 says, "Polypropylene has been used as a mesh for</p> <p>11 hernia repairs since 1958."</p> <p>12 My question, sir, is do you have any</p> <p>13 criticisms of Ethicon's hernia mesh?</p> <p>14 A. My -- my opinions about hernia mesh are</p> <p>15 similar to the sutures. It's implanted in a</p> <p>16 different part of the body. Because it's made from</p> <p>17 polypropylene, it will be subjected to these same</p> <p>18 reactions. But because it's in a different part of</p> <p>19 the body, the clinical implications are different,</p> <p>20 and that's not the subject of my report, what</p> <p>21 happens to a hernia mesh if it's oxidized and</p> <p>22 degraded. That's not --</p> <p>23 Q. Sir, is it your testimony that every</p> <p>24 person has -- that has a hernia PROLENE mesh</p> | <p style="text-align: right;">Page 133</p> <p>1 of to what extent that oxidation has occurred,</p> <p>2 correct?</p> <p>3 A. I want to be very clear about this.</p> <p>4 I -- the science -- the science tells us that</p> <p>5 this -- you would expect this material to oxidize.</p> <p>6 I've not measured it, but I believe the science</p> <p>7 tells us that will happen. And to what extent is</p> <p>8 going to depend on other factors. I -- I -- it's</p> <p>9 possible -- I can't predict it. It's</p> <p>10 unpredictable, the extent of the oxidation and the</p> <p>11 clinical significance. But I believe that the</p> <p>12 chemistry, to a reasonable degree of scientific</p> <p>13 certainty, tells us that these materials will</p> <p>14 oxidize when implanted in the body.</p> <p>15 Q. And every person that has a hernia mesh</p> <p>16 that's made out of PROLENE has oxidized material in</p> <p>17 their body; it's just a -- it's just a matter of to</p> <p>18 what degree; is that fair?</p> <p>19 A. I mean, when exactly these reactions</p> <p>20 start is not exactly clear, so there is some time</p> <p>21 that it takes to happen. But, you know, I believe</p> <p>22 these materials will oxidize. It's just --</p> <p>23 Q. How long does it take to happen?</p> <p>24 A. It's unpredictable. It depends on the</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 134</p> <p>1 anatomic site. It depends possibly on the patient. 2 It depends on lots of factors, but it's something 3 that you can't predict, and it's something you 4 can't design for. 5 Q. If we look at Exhibit 6 to your 6 deposition -- 7 A. Okay. 8 Q. -- none of the specimens that Imel, 9 I-m-e-l, studied were PROLENE, were they? 10 A. These were Boston Scientific meshes, so 11 they -- they did not include PROLENE. 12 Q. And when a medical device is first 13 implanted in the body, it comes in contact with 14 body fluids, fair to say? 15 A. Yes. 16 Q. And macrophages are some of those body 17 fluids. 18 A. Well, macrophage is a cell, not a 19 fluid. 20 Q. Okay. Or -- or body -- body material. 21 And macrophages contain proteins, correct? 22 A. Well, I mean, all cells contain 23 proteins, but it's a -- it's a cell. I mean, a 24 cell --</p> | <p style="text-align: right;">Page 136</p> <p>1 protein can -- 2 Q. That's with a D. 3 A. With a D. Yeah. Sorry. 4 Can the adsorbed proteins be removed 5 mechanically? Is that what you mean? 6 Q. Yes, sir. 7 A. Probably not. It's -- 8 Q. It -- it would be a chemical -- it 9 would have to be a chemical reaction or a chemical 10 protocol to remove the proteins; is that right? 11 A. Typically, you would -- you could 12 desorb them, you could break them with a 13 proteinase. Yeah. Something not mechanical. 14 Q. Okay. And, Doctor, do you know how to 15 remove proteins from a medical device after it's 16 taken out of the body? 17 A. Well, in my work, we're more concerned 18 with removing cells. So we'll use different 19 enzymes and -- and materials to remove the cells 20 from the material. 21 Q. Do you know how to clean and remove 22 proteins from an explanted piece of mesh, from a 23 chemical standpoint? 24 A. I thought I answered it; but, I mean, I</p> |
| <p style="text-align: right;">Page 135</p> <p>1 Q. But -- but we can agree that proteins 2 adsorb to the surface of the medical implant, 3 correct? 4 A. Well, the -- the proteins adsorb to 5 facilitate cell attachment. I mean, that the 6 adsorbed proteins facilitate -- 7 Q. And -- 8 A. -- the attachment to cells. 9 Q. And that occurs -- and that reaction 10 occurs within seconds of the implant; is that 11 right? 12 A. Proteins adsorb very -- fast, yeah. 13 Q. Can proteins be removed manually from 14 the explant? 15 MR. BOWMAN: Object to form. 16 BY MR. HUTCHINSON: 17 Q. Once it's taken out of the body? 18 A. Manually? What do you mean by 19 "manually"? 20 Q. Can they be scrubbed off? Can they be 21 removed with tweezers? 22 A. I mean, tissue can. 23 Q. But the protein, sir, is my question. 24 A. The adsorbed proteins? I mean, this</p> | <p style="text-align: right;">Page 137</p> <p>1 know Dr. Timms used proteinase. A lot of people 2 are using -- 3 Q. I know what they do. 4 A. Yeah. 5 Q. But I'm asking what you know. 6 A. Well, I haven't specifically -- 7 Q. Okay. 8 A. -- done that. Like I said, I'm 9 typically removing cells. But you still have to 10 digest the matrix. So we add these types of -- 11 because the cells are embedded in some matrix, and 12 if you want the cells, you have to digest the 13 matrix. 14 Q. And, Doctor, you'll agree that an 15 increased layer of proteins can build up on a 16 foreign body object over time? 17 A. Yeah, protein adsorption is typically 18 going to reach some equilibrium. Now -- 19 Q. But it will build up over time. The 20 proteins will build up on a medical device over 21 time? 22 A. I would like to be a little more 23 specific in my answer, if I could. The -- the 24 proteins will adsorb which can facilitate cell</p> |

35 (Pages 134 to 137)

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 138</p> <p>1 attachment and cells can deposit matrix and that 2 combined -- it's a very complex event. It's not -- 3 it's not a -- you know, I -- I guess -- I don't 4 know that -- I mean, my understanding of protein 5 adsorption is, if you're going to reach some 6 equilibrium, there's going to be some competitive 7 adsorption with different proteins. But the 8 over-time part, to me, would be more matrix 9 deposition by the cells. 10 Q. On page 1 of Exhibit 6 -- 11 A. Okay. 12 Q. -- we talked about polypropylene being 13 used as a mesh for hernia repairs since the 1950s. 14 Doctor, does the pelvic region have 15 more reactive oxygen species than the abdomen? Or 16 do you know? 17 MR. BOWMAN: Object to form. 18 THE WITNESS: There have been some -- 19 there's -- I know there's one paper that's been 20 published about the increased prevalence of the -- 21 of ROS, things like peroxides in the vaginal space. 22 BY MR. HUTCHINSON: 23 Q. But can you quantify reactive oxygen 24 species found in the pelvic region?</p> | <p style="text-align: right;">Page 140</p> <p>1 peroxides that are secreted in vivo? 2 A. Well, maybe we can make this a little 3 faster by -- all of these reactive oxygen 4 species -- how much is secreted by adherent cells 5 on the mesh, that's not been measured, but, again, 6 it's a very localized environment. There's an 7 adherent cell on the surface and that 8 microenvironment is different from the broader 9 tissue microenvironment. 10 So it's difficult to know exactly what 11 the composition of that -- we know what's in it. 12 That's why the simulated oxidation test was 13 developed. But the exact concentrations of all 14 those species are difficult to know. 15 Q. In fact, you don't know those exact 16 concentrations of all those species sitting here 17 today, do you? 18 MR. BOWMAN: Asked and answered. 19 THE WITNESS: I mean, I thought I 20 answered it. Not for -- I mean, not -- for this 21 adherent macrophage on the surface of the 22 polypropylene, I don't -- I don't know what the 23 concentrations of all these relative species are, 24 but they're there.</p> |
| <p style="text-align: right;">Page 139</p> <p>1 A. I've -- I mean, I've not done that, but 2 I believe this paper -- I would have to review the 3 paper to see exactly what -- but I believe it has 4 been looked at. 5 Q. What's the name of the paper? 6 A. I just can't remember right now. 7 Q. Is it cited in your report that we've 8 marked as Exhibit 2 to your deposition? 9 A. It's probably on the reliance list. I 10 would have to check. I just don't remember. I 11 wasn't -- yeah. 12 Q. Doctor, sitting here today, can you 13 quantify -- without looking at your literature, can 14 you quantify the reactive oxygen species found in 15 the pelvic region? 16 A. I've not done that. 17 Q. Doctor, can you tell us the amount of 18 peroxides that are secreted in vivo? 19 A. Well, it's not just peroxides. It's 20 hydroxyl radicles, hypochlorous acid. There's a 21 lot of these reactive oxygen species that are 22 secreted by different types of cells. 23 Q. Okay. Well, let's take -- let's take 24 one by one. Can you tell us the amount of</p> | <p style="text-align: right;">Page 141</p> <p>1 BY MR. HUTCHINSON: 2 Q. But -- and, sir, do you have -- can you 3 give us a percentage? 4 A. I -- I -- I -- I don't know. I'd have 5 to look at some papers. I don't know the -- the 6 exact composition of that. 7 Q. And how -- how do they -- how does that 8 compare to 30 percent hydrogen peroxide? 9 A. Well, that's -- that test is -- you're 10 referring to -- okay. I'm confused. Are you 11 referring to just 30 percent hydrogen peroxide or 12 with the cobalt catalyst? I'm not -- I'm not 13 sure -- 14 Q. The 20 percent. Let's use 20 percent. 15 A. Just the hydrogen peroxide? 16 Q. Uh-huh. 17 A. Well, I mean, that test was done to 18 give some estimate of what the effects could be. 19 Q. And -- and, Doctor, you'll agree that 20 20 percent hydrogen peroxide is higher than what is 21 usually seen in a clinical setting in the body? 22 A. Well, I think that's a very vaguely 23 stated -- the -- again, these -- these compositions 24 are in a -- are in a privileged microenvironment.</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 142</p> <p>1 There's a pocket between the adherent macrophage 2 and the surface of the material. 3 Q. Right. 4 A. So the composition there in that 5 microenvironment is different than -- and that's 6 the concentration that matters because that's what 7 the polypropylene is exposed to. 8 Q. I understand. 9 A. So the concentration everywhere else in 10 the body doesn't really matter -- 11 Q. Doctor -- 12 A. -- as much. 13 Q. -- do you have any idea how much 14 hydrogen peroxide is produced by the body in a 15 foreign response -- foreign -- in a foreign body 16 response to any of these nine products that we're 17 here today on? 18 A. Again, I thought I've answered that. 19 It's this -- there's this microenvironment, and how 20 much hydrogen peroxide is in there is -- is not -- 21 I don't -- I can't -- I just can't answer that 22 right now without looking at some studies. 23 Q. Okay. And, Doctor, what studies would 24 you need to look at?</p> | <p style="text-align: right;">Page 144</p> <p>1 over the body. 2 BY MR. HUTCHINSON: 3 Q. Okay. And, Doctor, can you tell us how 4 much hydrogen peroxide would be needed to oxidize 5 PROLENE in vivo? 6 MR. BOWMAN: Object to form. 7 THE WITNESS: Again, it's a question of 8 rate. The more hydrogen peroxide, other oxidative 9 species, the faster it's going to occur. What 10 exactly those concentrations are, I don't know that 11 it's been studied for polypropylene oxidation, 12 what -- what those concentrations are. 13 BY MR. HUTCHINSON: 14 Q. And I'm not asking about polypropylene 15 oxidation. I'm talking about PROLENE oxidation. 16 So let's be clear. 17 A. PROLENE's -- 18 Q. Hold on just a minute. Let me finish 19 my question. 20 A. I thought you were finished. 21 Q. Doctor, can you tell us how much 22 hydrogen peroxide would cause PROLENE to oxidize in 23 vivo? 24 MR. BOWMAN: Object to form.</p> |
| <p style="text-align: right;">Page 143</p> <p>1 A. I'd have to -- I just don't -- I'd have 2 to look for some papers on that. I don't -- I 3 don't -- I don't know -- I don't have it in my 4 memory what -- 5 Q. Are those paper on your reliance list? 6 A. I don't know. 7 Q. Doctor, you'll agree that 20 percent 8 hydrogen peroxide is higher than what is usually 9 seen in a clinical setting? 10 A. I'm not going to agree with that. You 11 can keep asking it over and over. I'm not going to 12 agree with it. Because "clinical setting" is a 13 vague term. 14 Clinical setting, are you talking about 15 everywhere in the body or are you talking about 16 that specific microenvironment between the cell and 17 the biomaterial? I mean, it's -- it's -- it's too 18 vague of a question. 19 Q. Do you know how many micromoles of 20 hydrogen peroxide are found in the body? 21 MR. BOWMAN: Object to form. 22 THE WITNESS: Again, it's too vague of 23 a question. What's in the body -- what matters is 24 what's in that microenvironment, not what's all</p> | <p style="text-align: right;">Page 145</p> <p>1 THE WITNESS: I would answer it the 2 same -- there's that microenvironment and how much 3 hydrogen peroxide is in there is -- I -- I don't 4 know. If there's some, it will oxidize. But if 5 it's going to -- it's a question of concentration. 6 The more that's there, the more it's going to 7 oxidize. 8 BY MR. HUTCHINSON: 9 Q. You can't tell us how much hypochlorous 10 acids would cause PROLENE to oxidize in the body, 11 can you? 12 MR. BOWMAN: Object to form. He's -- 13 he's already made it clear that he's talking about 14 concentrations and not -- 15 MR. HUTCHINSON: Understood. 16 Understood. 17 MR. BOWMAN: Okay. 18 MR. HUTCHINSON: Understood. 19 THE WITNESS: I'm just going to keep 20 saying -- 21 BY MR. HUTCHINSON: 22 Q. Same question with hydrochloric acid. 23 A. So hydrochloric acid, again, it's -- 24 Q. Can you tell us how much would cause</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 146</p> <p>1 PROLENE to oxidize?</p> <p>2 A. Well, I don't know that hydrochloric</p> <p>3 acid would cause oxidation. I mean, polypropylene</p> <p>4 is relatively resistant to acids and bases. It's</p> <p>5 the oxidizers that it's not. So I would say that</p> <p>6 all of these reactive oxygen species are -- are --</p> <p>7 you know, they're present in that privileged</p> <p>8 microenvironment, and they're going to cause</p> <p>9 oxidation. That's what we know.</p> <p>10 Q. But you can't tell us how much is</p> <p>11 required to cause oxidation, can you, is my</p> <p>12 question?</p> <p>13 MR. BOWMAN: Object to the form.</p> <p>14 THE WITNESS: I feel like I've answered</p> <p>15 it. If it's there, it will cause oxidation.</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. I understand.</p> <p>18 A. It's a question of the rate and the</p> <p>19 extent.</p> <p>20 Q. But can you tell us how -- how much</p> <p>21 will cause oxidation? That's my question.</p> <p>22 A. If there's some there, it will cause</p> <p>23 oxidation. It's just a question of the extent. So</p> <p>24 if there's more or less, there will be more or less</p> | <p style="text-align: right;">Page 148</p> <p>1 Q. Can you answer that question, Doctor?</p> <p>2 A. I'm going to answer it the same way</p> <p>3 I've been answering it. That if there is reactive</p> <p>4 oxygen species in that privileged microenvironment,</p> <p>5 there will be -- you would expect there to be</p> <p>6 oxidation going on, and it's a question of</p> <p>7 concentration. The more that's there, the more</p> <p>8 oxidation you're going to get.</p> <p>9 Q. And can you quantify -- and strike</p> <p>10 that.</p> <p>11 And can you quantify that</p> <p>12 concentration?</p> <p>13 MR. BOWMAN: Object to the form. Asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: I don't know, off the top</p> <p>16 of my head, by my memory, what the concentrations</p> <p>17 of those reactive oxygen species are. I think you</p> <p>18 asked me about that already. But I know that</p> <p>19 they're there. And I -- and that -- they're there.</p> <p>20 Those reactions would be expected to occur.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Doctor, let's go back to Sanotox R and</p> <p>23 DLTDP. Do you have criticisms of Ethicon for using</p> <p>24 those two specific antioxidants in their</p> |
| <p style="text-align: right;">Page 147</p> <p>1 oxidation. But if the reactive oxygen species are</p> <p>2 there, you would expect these reactions to be going</p> <p>3 on. I guess I'm really. . .</p> <p>4 Q. That's fine.</p> <p>5 MR. HUTCHINSON: Move to strike as</p> <p>6 nonresponsive.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. My question to you, sir, is can you</p> <p>9 tell us how much would cause PROLENE to oxidize in</p> <p>10 the body?</p> <p>11 A. And I believe I've answered --</p> <p>12 MR. BOWMAN: Objection --</p> <p>13 THE WITNESS: -- that question multiple</p> <p>14 times.</p> <p>15 (Simultaneous speaking.)</p> <p>16 (Reporter interruption for</p> <p>17 clarification.)</p> <p>18 MR. BOWMAN: I have to object as</p> <p>19 compound and vague. He's already made it clear</p> <p>20 that he's asking -- he wants you to include</p> <p>21 concentrations in -- in the amount of material</p> <p>22 that's -- that's going to be oxidized, that kind of</p> <p>23 thing.</p> <p>24 BY MR. HUTCHINSON:</p> | <p style="text-align: right;">Page 149</p> <p>1 formulation of PROLENE?</p> <p>2 A. I believe my opinion on this matter is</p> <p>3 that those antioxidants were added to protect the</p> <p>4 polypropylene during the manufacturing process and</p> <p>5 whether or not they're doing anything -- protecting</p> <p>6 any in vivo oxidation was not looked at very much.</p> <p>7 There are some studies where they show depletion of</p> <p>8 oxidation in the -- depletion of antioxidants in</p> <p>9 the oxidized polypropylene on the surface.</p> <p>10 Q. Okay. But my question is are you</p> <p>11 criticizing Ethicon for using DLTDP and Sanotox R</p> <p>12 in the formulation of PROLENE?</p> <p>13 MR. BOWMAN: Object to form.</p> <p>14 THE WITNESS: Are you asking</p> <p>15 criticizing the selection of those?</p> <p>16 BY MR. HUTCHINSON:</p> <p>17 Q. (Indicating yes.)</p> <p>18 A. I don't know how to answer it, other</p> <p>19 than I did. Those antioxidants were chosen for</p> <p>20 stabilization during manufacturing and storage, not</p> <p>21 for in vivo use. That's -- that's my opinion.</p> <p>22 Q. So --</p> <p>23 A. And they're well known to stabilize --</p> <p>24 I mean, they're well known stabilizers for</p> |

Scott Guelcher

| | |
|---|---|
| <p style="text-align: right;">Page 150</p> <p>1 manufacturing purposes, but not for -- necessarily 2 for in vivo oxidation. 3 Q. Doctor, but that's not my question. 4 Are you criticizing Ethicon for selecting Sanotox R 5 and DLTD as two antioxidants used in the 6 formulation of PROLENE? 7 MR. BOWMAN: Object to form. Asked and 8 answered. 9 THE WITNESS: Again, I believe I've 10 answered it. I'm not -- 11 BY MR. HUTCHINSON: 12 Q. And in all due respect -- in all due 13 respect, Doctor, you haven't. I'm just -- do you 14 criticize Ethicon? That's all my question -- 15 MR. BOWMAN: He did answer that today, 16 and he's already testified about this in the Huskey 17 case. And -- but he has -- 18 THE WITNESS: I'll try one more time. 19 So those two antioxidants are well known for 20 protecting polypropylene during manufacturing. I'm 21 not -- 22 MR. HUTCHINSON: And move it strike as 23 nonresponsive. 24 BY MR. HUTCHINSON:</p> | <p style="text-align: right;">Page 152</p> <p>1 complex matter. There are many different 2 combinations that can be used. Just because a 3 certain set of antioxidants is useful for 4 protecting during manufacturing and -- and 5 long-term storage doesn't mean they'll be effective 6 in the body. That needs to be studied with in vivo 7 studies and perhaps testing different 8 concentrations, different types of antioxidants. 9 My -- my criticism has been that that 10 work has not been done, at least to a very 11 extensive degree, other than that study that showed 12 antioxidant depletion in the -- in the oxidized 13 polypropylene. 14 Q. Doctor, can you tell us the names of -- 15 of the antioxidants that you believe Ethicon should 16 have used? 17 A. I believe I just answered your 18 question. I'm not -- I'm not proposing any 19 specific set of antioxidants. I'm saying that 20 studies should have been done to consider different 21 combinations, different formulations other than 22 just protecting it during the manufacturing 23 process. 24 Q. And do you have any alternatives,</p> |
| <p style="text-align: right;">Page 151</p> <p>1 Q. I'm not asking you how well known they 2 are. I'm asking you if criticize Ethicon for 3 selecting -- 4 A. I was trying to finish. Just let me 5 finish. 6 Q. All right. But please answer the 7 question. 8 A. Just -- 9 Q. Do you criticize Ethicon for selecting 10 DLTD and Sanotox R as antioxidants? 11 A. I'm -- I'm not criticizing them for 12 using those in the manufacturing process. I am 13 criticizing the logic that they're going to be 14 effective in vivo because that was never really 15 looked at carefully. 16 Q. Do you have a solution? 17 A. I'm not proposing a solution. I'm 18 not -- I'm not providing an opinion other than 19 that -- that that should be looked at, what -- how 20 effective are these antioxidants in vivo. That's 21 my opinion. 22 Q. And what's the alternative to these 23 antioxidants, Doctor? 24 A. Well, antioxidants are a -- are a</p> | <p style="text-align: right;">Page 153</p> <p>1 sitting here today, to Sanotox R and DLTD? 2 A. I'm not proposing alternatives. Those 3 two antioxidants could have been studied in vivo, 4 or they could have looked at other antioxidants. 5 There -- but -- but that wasn't done. That's -- 6 that's my opinion, that I've stated many times in 7 trial and depositions and courts, and that hasn't 8 changed. 9 Q. Doctor, if we look the Imel study that 10 we've marked as Exhibit 6 -- 11 A. Exhibit 6, that's -- those are -- I'm 12 sorry. You said what? Oh, Imel. 13 Q. Yeah. I-m-e-l. 14 A. I thought you said animal. Sorry. 15 Q. That's okay. Are you there with me? 16 A. I am. 17 Q. The fibers from these mesh explants 18 were not 100 percent cleaned of proteins, were 19 they? 20 A. I don't know how to answer that. In 21 this study, he found regions of oxidized 22 polypropylene that had no protein because there was 23 no nitrogen present, and he found regions where 24 there appeared to be a mix of oxidized</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 154</p> <p>1 polypropylene and protein. So there were regions 2 where there were still adsorbed proteins, but there 3 are regions where there were not. That's what he 4 reports in the study. 5 Q. Okay. And, Doctor, he also reports in 6 this study a carbonyl peak at 1740; is that right? 7 A. In the IR spectra and his supplemental 8 data, he's seen a carbonyl peak at 1740 that's not 9 in the explants -- I'm sorry -- that's not in 10 the nonimplanted exemplars, but it -- it does 11 appear in the explants. 12 Q. Doctor, do you know where DLTDP has 13 a -- has a FTIR spectra showing up on the -- 14 A. There's some -- 15 Q. -- on the reciprocal centimeter line? 16 A. There is some internal Ethicon 17 documents that reported in that range. 18 Q. In 1740? 19 A. Uh-huh. I think so. 20 Q. Is that a "yes"? 21 A. Yes, that's what I remember. 22 Q. Okay. 23 A. There are some internal Ethicon 24 documents that show depletion, but when they took</p> | <p style="text-align: right;">Page 156</p> <p>1 I mean, it depends on the product and what it's 2 supposed to do, where it's implanted, what -- what 3 the expected response is. 4 MR. HUTCHINSON: Move to strike as 5 nonresponsive. 6 And this is not going to count as my 7 time. I mean, it's a very clear question. 8 BY MR. HUTCHINSON: 9 Q. My question to you is are you aware of 10 any medical device on the market that will never 11 oxidize? 12 A. This is such an extreme question. I 13 don't -- I don't know. I mean, there are -- there 14 are materials that oxidize -- that -- that oxidize 15 very slowly or not much at all that can be 16 measured, but -- I mean, there's a lot of 17 biomedical devices on the market. I haven't looked 18 at that specific question. 19 Q. Can you answer that question, Doctor, 20 sitting here today? 21 A. A device that's never oxidized? I 22 don't know. I mean, I'd have to look into that. 23 This is so broad. It's hard to answer. 24 Q. Doctor, can you tell me the name of a</p> |
| <p style="text-align: right;">Page 155</p> <p>1 those IR spectra, they blew them way up so the 2 normal -- the peaks are very small. They're 3 difficult to see. 4 Q. Doctor, have -- and I may have asked 5 you this earlier. Have you ever designed a medical 6 device product? 7 A. Have I ever designed a medical device 8 product? In my research, I work with device 9 companies on -- I have work ongoing in that area. 10 Q. And do any of the products that you 11 have worked on have a lifetime warranty? 12 A. Lifetime warranty? I mean, these are 13 degradable grafts. So they're intended to -- 14 Q. The products that you're working on? 15 A. Yes. 16 Q. Okay. 17 A. So they're intended to be replaced by 18 tissue over time and go away. 19 Q. Doctor, are you aware of any medical 20 product on the market that will never oxidize? 21 A. Wow. That's a really broad question. 22 A product that will never oxidize? I don't know. 23 MR. BOWMAN: Object to form. 24 THE WITNESS: That's so vague. I...</p> | <p style="text-align: right;">Page 157</p> <p>1 medical device on the market that will never 2 oxidize? 3 A. And, again, it's a -- it's just a -- I 4 don't know how to answer that. That's a broad 5 question. Never oxidize. I don't -- I don't know. 6 MR. HUTCHINSON: Move to strike 7 everything before "I don't know." 8 BY MR. HUTCHINSON: 9 Q. Doctor, are you aware of any foreign 10 body material that will never oxidize in the body? 11 A. Any foreign body material? 12 Q. That will never oxidize in the body. 13 A. I don't know. Again, it's -- it's 14 extremes of oxidation. I mean, it's -- it's -- 15 these are misleading questions. I don't -- I don't 16 know of any material that just doesn't oxidize. 17 I'd have to -- I don't know. 18 MR. HUTCHINSON: And move to strike 19 everything other than I don't know any material 20 that doesn't oxidize. 21 BY MR. HUTCHINSON: 22 Q. Doctor, can oxidation in pelvic mesh 23 ever be completely eliminated? 24 A. Can oxidation in pelvic mesh be</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 158</p> <p>1 completely eliminated? I mean, I think it's in my 2 report. No. These -- these antioxidants -- 3 Q. It's not in your report. 4 A. It is in my report. 5 Q. Listen to my question. 6 A. Okay. 7 Q. Can oxidation of pelvic mesh ever be 8 completely eliminated? That's the question. 9 MR. BOWMAN: Object to form. 10 THE WITNESS: I believe it's in my 11 report. I -- the antioxidants are depleted over 12 time. The mesh oxidizes. And the clinical 13 implications are unpredictable. You can't design 14 for it. That's my answer. 15 BY MR. HUTCHINSON: 16 Q. My -- my question is can oxidation of 17 pelvic mesh ever be completely eliminated? 18 A. I just answered it. The antioxidants 19 deplete over time, and the mesh will oxidize as 20 they're depleted, and that's going to lead to these 21 other events that are unpredictable. That's the 22 answer to the question. 23 Q. So it can be completely eliminated in 24 pelvic mesh?</p> | <p style="text-align: right;">Page 160</p> <p>1 can oxidize. 2 BY MR. HUTCHINSON: 3 Q. But can oxidation ever be completely 4 eliminated, sir? 5 A. As the antioxidants are depleted, 6 oxidation of the mesh would be expected to occur. 7 I don't know what else to say. 8 Q. My question is can it ever be 9 completely eliminated? 10 A. As the antioxidants are depleted in the 11 mesh, the polypropylene would oxidize. 12 MR. HUTCHINSON: Move to strike as 13 nonresponsive. 14 BY MR. HUTCHINSON: 15 Q. My question is -- 16 MR. BOWMAN: He's actually answered 17 this question. 18 MR. HUTCHINSON: No, he hasn't. My 19 question is -- 20 MR. BOWMAN: He said he wasn't giving 21 you any -- 22 (Simultaneous speaking.) 23 THE WITNESS: We can sit here for -- 24 (Reporter interruption for</p> |
| <p style="text-align: right;">Page 159</p> <p>1 A. I answered the question. I don't 2 really want to play this game. 3 THE WITNESS: Can I -- can we take a 4 break again? I -- 5 BY MR. HUTCHINSON: 6 Q. No. I need the question answered first 7 and then we'll take a break. 8 A. We can answer it for an hour. I'm 9 going to give you the same answer I just gave you. 10 I feel like I've made these opinions very clear. 11 Q. My question is can oxidation of pelvic 12 mesh ever be completely eliminated? Yes or no? 13 MR. BOWMAN: Object to form. 14 THE WITNESS: The antioxidants are 15 depleted. As the antioxidants are depleted, you 16 expect oxidation of the polypropylene in the mesh, 17 which can lead to these other unpredictable events. 18 BY MR. HUTCHINSON: 19 Q. But can it ever be completely 20 eliminated? That is my question. 21 A. The antioxidants are -- 22 MR. BOWMAN: Object to form. 23 THE WITNESS: -- depleted over time. 24 As they're depleted, the polypropylene in the mesh</p> | <p style="text-align: right;">Page 161</p> <p>1 clarification.) 2 THE WITNESS: We can sit here for an 3 hour if you want. I mean, it's over at 1:00. 4 As the antioxidants are depleted -- 5 MR. HUTCHINSON: And move to strike as 6 nonresponsive. 7 THE WITNESS: -- the polypropylene -- 8 BY MR. HUTCHINSON: 9 Q. I'm trying to be respectful to you, 10 Doctor. 11 MR. BOWMAN: No, wait a minute. I need 12 to -- 13 MR. HUTCHINSON: Then we'll take a 14 break. 15 MR. BOWMAN: I need to get my objection 16 on the record. He's already said he's not offering 17 you alternatives. He's telling you what's going on 18 with the pelvic mesh that's involved here. All 19 right? Now I'm going to object as asked an 20 answered. 21 And if you want to rephrase the 22 question, go ahead. 23 MR. HUTCHINSON: All right. 24 BY MR. HUTCHINSON:</p> |

41 (Pages 158 to 161)

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 162</p> <p>1 Q. I'm asking, Doctor, can it ever 2 be completely -- can oxidation ever be completely 3 eliminated? 4 MR. BOWMAN: I'm going to instruct you 5 not to answer. 6 THE WITNESS: I'm not going to answer. 7 BY MR. HUTCHINSON: 8 Q. Doctor, are you giving any alternatives 9 to PROLENE mesh? And your counsel said no. I just 10 want to make sure, and then we'll take a break. 11 MR. BOWMAN: Object to form. 12 BY MR. HUTCHINSON: 13 Q. Are you giving any alternatives to 14 PROLENE mesh? 15 A. I've not opined that there are 16 alternatives to PROLENE mesh. My opinions relate 17 to what happens to PROLENE implanted in the body. 18 Q. And I understand that. I know there's 19 none in your report. But are you giving, here 20 today, any opinions? 21 A. I -- I just said that. I'm not giving 22 any opinions about alternatives to PROLENE mesh. 23 I'm stating what happens to PROLENE mesh in the 24 body.</p> | <p style="text-align: right;">Page 164</p> <p>1 changed? 2 A. Other than what I said before, I 3 believe more testing could have been done to 4 address the question of oxidation, degradation and 5 the clinical implications of that and bench scale 6 testing, preclinical testing could have been done 7 to answer that question. That's also in my report. 8 Q. All right. But outside of more 9 testing -- I want to talk about specifically how 10 you believe Ethicon's nine different products 11 should be significantly changed. Do you have any 12 opinions of how they should be changed? 13 A. How they should be changed? 14 Q. Yes, sir. These nine different 15 products. 16 A. Well, conceptually, they could be made 17 more resistant to in vivo oxidation by looking at 18 the antioxidant package. That could be an 19 improvement. That's consistent with my opinions. 20 Q. And, Doctor, how would you make the 21 mesh in these nine products more resistant to in 22 vivo oxidation? 23 A. I think it needs to be studied. You 24 would have to do testing to identify an antioxidant</p> |
| <p style="text-align: right;">Page 163</p> <p>1 MR. HUTCHINSON: Okay. We can take a 2 break. 3 MR. BOWMAN: All right. 4 (Brief recess.) 5 MR. HUTCHINSON: Doctor, we're back on 6 the record. Are you ready to go? 7 THE WITNESS: Yes. 8 BY MR. HUTCHINSON: 9 Q. Is there anything -- have you 10 understood all my questions so far? 11 A. Most of them. 12 Q. Have you -- is there anything about the 13 testimony that you have given that you would like 14 to change? 15 A. No. 16 Q. Doctor, do you have any opinions about 17 how Ethicon's nine products should be changed or 18 modified in the way they are manufactured, and if 19 so, how? 20 A. Specific to manufacturing, no. I don't 21 have any opinions about the manufacturing of the 22 devices. 23 Q. Do you have any opinions about how 24 Ethicon's nine products should be significantly</p> | <p style="text-align: right;">Page 165</p> <p>1 package that's effective in vivo. I -- I don't 2 know a specific package without doing testing. 3 Q. Doctor, on -- let's talk about the 4 women on Exhibit Number 1 that you're here to 5 testify for. 6 A. Okay. What about the doctors for any 7 of these women? Did any of these doctors commit 8 malpractice by using these Ethicon products in 9 pelvic floor repair? 10 MR. BOWMAN: Object to form. 11 THE WITNESS: I've not expressed any 12 opinion about the conduct of the doctors in 13 implanting these women. I -- I have no opinion 14 about the doctors. 15 BY MR. HUTCHINSON: 16 Q. And, Doctor, do you believe that these 17 doctors who implanted these Ethicon products in 18 these women did anything wrong? 19 MR. BOWMAN: Object to form. 20 THE WITNESS: I've not opined that 21 they've done anything wrong. They implanted the 22 device. I don't know how it was implanted. I 23 don't know when. I haven't reviewed the medical 24 records. So I have no way to assess the conduct of</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 166</p> <p>1 the doctors.</p> <p>2 MR. HUTCHINSON: And, Doctor, we'll</p> <p>3 hand you what we'll mark as Exhibit 7 to your</p> <p>4 deposition.</p> <p>5 (Whereupon Exhibit 7 was marked as an</p> <p>6 exhibit.)</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. You've seen this study before, haven't</p> <p>9 you?</p> <p>10 A. Yes.</p> <p>11 Q. And this is the seven-year dog study</p> <p>12 done by Dan Burkley?</p> <p>13 A. It is.</p> <p>14 Q. And you've relied on this study in</p> <p>15 support of your opinions; is that correct?</p> <p>16 A. Yes.</p> <p>17 Q. And, Doctor, do you -- if you'll look</p> <p>18 with me, please, on page 09888221 -- 221 is the</p> <p>19 last. . .</p> <p>20 A. 09888221?</p> <p>21 Q. 221.</p> <p>22 A. Okay.</p> <p>23 Q. Down there at the bottom, it states</p> <p>24 under "Conclusions": "Comparison of 7-year</p> | <p style="text-align: right;">Page 168</p> <p>1 sampling problem?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: Well, I'll be more</p> <p>4 specific. They -- they sampled the whole fiber.</p> <p>5 Whereas, the molecular weight loss would be</p> <p>6 expected to occur near the surface of the fiber.</p> <p>7 And so if the bulk of the fiber had not yet</p> <p>8 degraded, you wouldn't see it, but you would still</p> <p>9 see the effects at the surface. You have to sample</p> <p>10 the polypropylene on the surface as they did in</p> <p>11 that human explant study. But in this I think it</p> <p>12 was just the bulk fiber.</p> <p>13 BY MR. HUTCHINSON:</p> <p>14 Q. And, Doctor, any time there's a chain</p> <p>15 scission, there's loss of molecular weight; is that</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And, Doctor, if you look at the</p> <p>19 seven-year dog study, other than -- other than a</p> <p>20 sampling size, do you have any other explanation of</p> <p>21 why --</p> <p>22 MR. HUTCHINSON: On page 221, Counsel.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. -- there was a finding of no molecular</p> |
| <p style="text-align: right;">Page 167</p> <p>1 explants to current PROLENE indicate no molecular</p> <p>2 weigh degradation."</p> <p>3 Did I read that correctly?</p> <p>4 A. That's what it says.</p> <p>5 Q. And, Doctor, do you have an explanation</p> <p>6 of why the findings in the Ethicon dog study showed</p> <p>7 no molecular weight degradation?</p> <p>8 MR. BOWMAN: Object to form. Misstates</p> <p>9 the document.</p> <p>10 THE WITNESS: Well, my understanding</p> <p>11 is, what they did in this study, they sampled the</p> <p>12 entire volume of the suture and the molecular</p> <p>13 weight degradation is occurring near the surface,</p> <p>14 in the outer layers. And so they may have not been</p> <p>15 able to detect it because mostly what they were</p> <p>16 testing was bulk polypropylene or PROLENE in the</p> <p>17 interior of the -- of the fiber.</p> <p>18 And so in the human explant study, they</p> <p>19 did see degradation on the surface, but in this</p> <p>20 study, it was -- it just might have been a sampling</p> <p>21 problem as to why they couldn't see the loss in</p> <p>22 molecular weight that I would expect.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Is that your explanation? It's a</p> | <p style="text-align: right;">Page 169</p> <p>1 weight degradation?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: You know, I do have some</p> <p>4 questions about the controls. You know, this --</p> <p>5 this control suture is, I don't think, the same as</p> <p>6 what was implanted.</p> <p>7 BY MR. HUTCHINSON:</p> <p>8 Q. It's just not the same size in</p> <p>9 diameter; is that correct?</p> <p>10 A. Well, it's -- it's -- it's current</p> <p>11 PROLENE 40. And so is that what was implanted</p> <p>12 seven years prior? I -- I don't know the answer to</p> <p>13 that.</p> <p>14 Q. Did you make any effort to find out?</p> <p>15 A. I -- I couldn't tell. I mean --</p> <p>16 Q. And, Doctor, you'll agree that the</p> <p>17 control they used was PROLENE, correct?</p> <p>18 A. It was PROLENE.</p> <p>19 Q. And, Doctor, if -- what did you notice</p> <p>20 about mechanical properties of the sutures after</p> <p>21 seven years of implantation?</p> <p>22 A. They didn't see changes in the</p> <p>23 strength, but, again, it's -- it's -- strength is a</p> <p>24 volume average quantity averaged over the entire</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 170</p> <p>1 volume of the suture, where these changes are 2 occurring at the surface. 3 Q. In fact, Doctor, the physical 4 properties -- or the mechanical properties, rather, 5 of the sutures increased after seven years, didn't 6 they? 7 A. I mean, can you -- what are you looking 8 at? I mean, can you -- I need to look at 9 specific -- to answer that. 10 Q. Did the -- well, did the mechanical 11 properties of the sutures increase after seven 12 years, Doctor? 13 A. I need to look at the -- the data 14 summary again. I need to look -- I need to refresh 15 myself with the data before I answer that. 16 So on page 11336182, there's the 17 seven-year data summary that includes the straight 18 strength, elongation and the modulus. 19 Q. Just focus on my question. 20 A. Well, I'm trying to answer it. I just 21 need to look at the data. 22 Q. You're just kind of reading aloud. 23 Just why don't you look at the data, and then let's 24 focus on my question.</p> | <p style="text-align: right;">Page 172</p> <p>1 Q. Okay. What about toughness? Is that a 2 mechanical property? 3 A. Well, it is, but it's not measured. 4 Q. Okay. 5 A. I mean, what's -- what's reported -- 6 Q. So -- 7 A. I'm going by what's reported, which is 8 the breaking strength, the elongation and the 9 Young's modulus. The breaking strength, as I said, 10 is staying about the same. The elongation is 11 getting longer and the modulus is going down. 12 Q. Okay. So let's just make sure you and 13 I are on the same page, Doctor. 14 A. Okay. 15 Q. If you can kind of just sit up and look 16 at me. 17 Breaking strength is a mechanical 18 property, correct? 19 A. It's a -- it's a -- it is a mechanical 20 property. 21 Q. Okay. Elongation -- elongation and 22 Young's modulus are also mechanical properties, 23 correct? 24 A. That's right.</p> |
| <p style="text-align: right;">Page 171</p> <p>1 A. Okay. I was trying to establish 2 where... so the PROLENE showed -- looks like 3 essentially not -- I mean, it's difficult to say 4 because there's no standard deviations here. So 5 what's significantly different -- I don't -- I 6 don't see standard deviations. But the PROLENE 7 sutures from zero to seven years, the changes in 8 the strength are pretty small. 9 Q. Okay. So, Doctor -- 10 MR. HUTCHINSON: So what was my 11 question? 12 THE WITNESS: Well, you said the -- 13 MR. HUTCHINSON: No. What's my 14 question? 15 (Whereupon the following question was 16 read back by the reporter: Did the -- well, did 17 the mechanical properties of the sutures increase 18 after seven years, Doctor?) 19 BY MR. HUTCHINSON: 20 Q. That's my question. 21 A. But "mechanical properties" is a broad 22 term. Mechanical properties would include breaking 23 strength, elongation, Young's modulus, that are 24 listed here.</p> | <p style="text-align: right;">Page 173</p> <p>1 Q. All right. So if we look at the 2 breaking strength of PROLENE, after seven years, it 3 decreased 5 percent from baseline; is that right? 4 A. That's the percentage that's shown. 5 Right. 6 Q. And elongation increased 111 percent; 7 is that right? 8 A. That's what it says. 9 Q. Any reason to disagree with that, 10 Doctor? 11 A. That's what they measured. I mean, 12 that's. . . 13 Q. In fact, any reason to disagree with 14 any of these numbers on page 183? 15 A. I mean, that's what's reported in the 16 study. 17 Q. Okay. And you -- 18 A. So that's what I'm going by. 19 Q. Right. And you have no reason to 20 believe that these numbers are incorrect; is that 21 right? 22 A. Not -- I mean, not incorrectly 23 measured. They -- 24 Q. And if we look at Young's modulus, the</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 174</p> <p>1 PROLENE decreased 70 percent; is that correct?</p> <p>2 A. That's right.</p> <p>3 Q. All right. And Young's modulus, that's</p> <p>4 just another word for stiffness; is that right?</p> <p>5 A. No. Stiffness is a different material</p> <p>6 property. Modulus is the initial slope</p> <p>7 approximately of the stress-strain curve. So it's</p> <p>8 a different property.</p> <p>9 Q. Right. And -- and, Doctor, what's your</p> <p>10 explanation for the increase -- mechanical -- or</p> <p>11 the improvement in the mechanical -- strike that.</p> <p>12 Doctor, what's your explanation for the</p> <p>13 improvement of the mechanical properties of the</p> <p>14 sutures from the seven-year dog study?</p> <p>15 A. I'm not sure why they're reporting this</p> <p>16 increase in elongation. I was looking mainly at</p> <p>17 the comments on degradation, oxidation. I'm not</p> <p>18 sure why they're reporting this increase in</p> <p>19 elongation at seven years.</p> <p>20 Q. Do you have an explanation?</p> <p>21 A. I just said I don't know why it's</p> <p>22 increasing at seven years.</p> <p>23 Q. All right. And, in fact, Doctor, you</p> <p>24 understood -- we talked about toughness earlier on;</p> | <p style="text-align: right;">Page 176</p> <p>1 Q. Yes, sir.</p> <p>2 A. Well, this is one point, right? So</p> <p>3 what's -- what you have here is initial slope,</p> <p>4 which would be the modulus, and then you've got a</p> <p>5 strength, which would be the -- the -- the endpoint</p> <p>6 of the test.</p> <p>7 Q. Okay. So if I understand correctly,</p> <p>8 what you would need is a stress-strain curve where</p> <p>9 breaking strength is the y-axis and elongation is</p> <p>10 the x-axis; is that right?</p> <p>11 A. No. The y-axis is the stress that's</p> <p>12 measured, and the x-axis is the strain --</p> <p>13 Q. Okay.</p> <p>14 A. -- or the elongation.</p> <p>15 Q. Okay.</p> <p>16 A. But it's not a -- what's reported here</p> <p>17 is the elongation at break, I believe --</p> <p>18 Q. And --</p> <p>19 A. -- strength at break.</p> <p>20 Q. And then what you would also need to</p> <p>21 look at is the area under the curve at time zero</p> <p>22 compared to the area under the curve at time -- at</p> <p>23 after year seven; is that right?</p> <p>24 A. No. Not really. I mean, it's -- it's</p> |
| <p style="text-align: right;">Page 175</p> <p>1 is that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know if these sutures in the</p> <p>4 seven-year dog study became tougher after seven</p> <p>5 years of implantation?</p> <p>6 A. They didn't report it. I mean, the</p> <p>7 toughness is the slope under the stress-strain</p> <p>8 curve, but that's difficult to assess because the</p> <p>9 elongation is going up, but the stress is -- looks</p> <p>10 like it's going down. So I -- they didn't report</p> <p>11 that. So I -- I can't comment on that.</p> <p>12 Q. Okay. And -- but how would you -- what</p> <p>13 would you need to be able to comment on toughness?</p> <p>14 Would you need a stress-strain curve plotting this</p> <p>15 out?</p> <p>16 A. That's --</p> <p>17 MR. BOWMAN: Object to form.</p> <p>18 THE WITNESS: -- one way to measure the</p> <p>19 toughness, is the area under the stress-strain</p> <p>20 curve.</p> <p>21 BY MR. HUTCHINSON:</p> <p>22 Q. Okay. And would you need any other</p> <p>23 data points on your stress-strain curve?</p> <p>24 A. Other data points on the curve?</p> | <p style="text-align: right;">Page 177</p> <p>1 a curve. So you can't -- oh -- okay. I think</p> <p>2 maybe I see what you're saying, look at the whole</p> <p>3 stress-strain curve measured at zero and then the</p> <p>4 whole curve measured --</p> <p>5 Q. Correct.</p> <p>6 A. -- at seven years.</p> <p>7 Q. That's correct.</p> <p>8 A. Yeah, I think that would give you the</p> <p>9 toughness.</p> <p>10 Q. Okay. And, in fact, if the area under</p> <p>11 the curve, after seven years, increased, that would</p> <p>12 mean the mechanical properties of the suture</p> <p>13 increased after seven years; is that right?</p> <p>14 A. No. It would mean that -- the</p> <p>15 toughness is measured -- approximated by the area</p> <p>16 under the curve was higher than if the area under</p> <p>17 the stress-strain curve is higher.</p> <p>18 Q. Okay. But we can assume that if the</p> <p>19 area under the curve, after seven years increased,</p> <p>20 then the sutures used in the dog study became</p> <p>21 tougher; we can agree to that?</p> <p>22 MR. BOWMAN: Object to form.</p> <p>23 THE WITNESS: I don't know. It's a</p> <p>24 strange finding. It's -- it's very surprising.</p> |

Scott Guelcher

Page 178

1 It's not -- it's -- I -- I have a difficult time --
 2 that just doesn't usually happen. It's --
 3 BY MR. HUTCHINSON:
 4 Q. But -- but my question is can you and I
 5 agree that if the area under the curve, after seven
 6 years, increased, then toughness of the sutures
 7 increased after seven years in the dog study?
 8 A. I don't know. I'd have to look at the
 9 data without answering that question. I don't -- I
 10 need to see -- I need to see those curves and look
 11 at it. It just wasn't calculated here. So I don't
 12 want to make inferences from their data something
 13 that wasn't reported.
 14 Q. Okay.
 15 A. I mean. . .
 16 Q. So you would need to see a
 17 stress-strain curve?
 18 A. Well, I need to see all the
 19 calculations to form an opinion. I'm just going by
 20 what was provided. And this is a strange result,
 21 that it doesn't do anything for two years and all
 22 of a sudden you go to two to seven years, there's
 23 this increase in elongation. It's very surprising.
 24 You know, I need to see more analysis to make

Page 179

1 conclusions about toughness and all those things.
 2 I mean, I just -- it's not in here, not in this
 3 document.
 4 MR. HUTCHINSON: Okay. Doctor, I'll
 5 hand you what we'll mark as Exhibit 8 to your
 6 deposition.
 7 (Whereupon Exhibit 8 was marked as an
 8 exhibit.)
 9 BY MR. HUTCHINSON:
 10 Q. This is a stress-strain curve where
 11 stress is the y-axis and strain is the x-axis. Do
 12 you see that?
 13 A. I do. But I have no idea where this
 14 came from. It's not in this document, and it's not
 15 in this report. And it's --
 16 Q. Well, stick with me on my questions for
 17 just a second. This shows toughness as -- under --
 18 as red at year zero using the same data points in
 19 the dog study; is that right?
 20 A. I don't know where this came from.
 21 This is --
 22 Q. I want you to compare it to the dog
 23 study.
 24 A. You just gave it --

Page 180

1 Q. And my question is are these the same
 2 numbers that are used in the dog study?
 3 A. I -- I don't -- I -- this just
 4 doesn't -- I don't -- I need to think about this.
 5 MR. BOWMAN: Yeah. I'm having trouble,
 6 actually, figuring out what you're talking about as
 7 well. Is there -- is there somewhere you could
 8 point to where this data is taken from?
 9 THE WITNESS: I need to see the data in
 10 this report. I need to see -- this is break
 11 strength versus elongation. I need to see the full
 12 stress-strain curve that was measured for these
 13 materials. That's how toughness is -- in my
 14 understanding, it's the stress-strain curve. This
 15 is the break strength versus percent elongation. I
 16 need to see the raw data where these -- from the
 17 actual test, the stress-strain curve that's used to
 18 get the toughness. But I -- I can't comment on
 19 this. This is break strength versus elongation
 20 which is -- it's a different concept than what I
 21 think of in terms of what I've done in my work, in
 22 my papers where you plot the stress versus the
 23 strain, and you calculate the area under the curve
 24 is the toughness. I --

Page 181

1 BY MR. HUTCHINSON:
 2 Q. In fact, Doctor, what we have here is
 3 breaking strength on the y-axis, correct?
 4 A. This is breaking strength. I'm --
 5 Q. All right. And then -- just stick with
 6 me and my questions and we'll get through this.
 7 We have elongation on the x-axis,
 8 correct?
 9 A. But elongation at what? Elongation at
 10 break? It just says "percent elongation."
 11 Q. And then, Doctor, my question to you is
 12 are these the same numbers on Exhibit 8 that are in
 13 the dog study for breaking strength and elongation?
 14 A. I -- I can't answer that question.
 15 It's --
 16 Q. Well --
 17 A. I can't pull numbers off of this graph
 18 and say that they're the same from this. I don't
 19 know where this came from. I mean, it's not
 20 plotted in the right way. It's not plotted as a --
 21 as a tensile strength versus strain. It's -- it's
 22 not plotted in a way that I'm accustomed -- so it's
 23 difficult to infer anything from this sort of
 24 analysis.

46 (Pages 178 to 181)

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 182</p> <p>1 Q. So, Doctor, at year zero, the breaking 2 strength of PROLENE was 1.68, correct? 3 A. Year zero, from the table it says 1.68. 4 Q. Right. And, in fact, Doctor, the 5 elongation at year seven was 1.6, correct? 6 A. Elongation at year seven? No. 7 Q. I'm sorry. The elongation at year -- 8 at time zero was 37; is that right? 9 A. That's the number in the table. But is 10 that elongation at break? I assume it is. That's 11 not the stress-strain curve. That's the terminal 12 point of the stress-strain curve. 13 Q. And, Doctor, stay with me. At year 14 seven, elongation is 78 percent; is that right? 15 A. That's what's listed in the table. 16 Q. And the table also lists at year seven 17 breaking strength at 1.6 pounds, correct? 18 A. That's the breaking strength. That's 19 the point at the end of the stress-strain curve and 20 my understanding the way they did this experiment. 21 Right? 22 Q. And the area under the curve at year 23 zero is smaller than the area under the curve at 24 year seven, isn't it?</p> | <p style="text-align: right;">Page 184</p> <p>1 A. I've not attempted to do it. They 2 report a strength. They report an elongation. They 3 report a modulus. There's this surprising increase 4 from year two to year seven, but -- 5 Q. And, Doctor, how would you create a 6 stress-strain curve to evaluate the toughness using 7 the information from the dog study? 8 MR. BOWMAN: Object to form. He just 9 testified that can't be done. 10 THE WITNESS: I can't make it from this 11 table. I would need to see the raw data. Maybe 12 it's in here. I don't know. I haven't -- I don't 13 know. 14 BY MR. HUTCHINSON: 15 Q. But have you looked for the raw data, 16 Doctor, that would support a stress-strain curve 17 analysis? 18 MR. BOWMAN: Object to form. Asked and 19 answered. 20 BY MR. HUTCHINSON: 21 Q. Have you looked for the data, Doctor? 22 A. I haven't looked for those data because 23 it's already shown in the table what I need to 24 know. There's a breaking strength. There's a</p> |
| <p style="text-align: right;">Page 183</p> <p>1 A. I'm not -- I cannot answer that 2 question. This is not -- in order to answer, I -- 3 I -- I don't want to be difficult. But in order to 4 answer this toughness question, I need to see raw 5 data. These are -- these are -- these -- these 6 data are plotted at the end of the experiment. I 7 need to see the actual stress-strain curve. I need 8 to know the stress at 1 percent elongation, 5 9 percent elongation, 10 percent, until it breaks. 10 And from that stress-strain curve, you can do more 11 analysis. 12 But this is simply a plot of break 13 strength versus elongation at break. And I -- I 14 can't make those kinds of inferences that you're 15 trying to get me to agree to. 16 Q. Well, Doctor, are you -- have you 17 attempted, in any way, to create a toughness curve 18 to measure the PROLENE sutures from the dog study 19 at year zero and year seven? 20 MR. BOWMAN: Object to form. 21 THE WITNESS: As I said -- 22 BY MR. HUTCHINSON, 23 Q. I'm asking you, have you attempted to 24 do that?</p> | <p style="text-align: right;">Page 185</p> <p>1 elongation. There's a modulus. And so I -- I see 2 the elongation and the modulus data at break. 3 Q. In fact, Doctor, can you explain the 4 elongation increase of 111 percent at year seven? 5 Can you explain that? 6 MR. BOWMAN: Object to form. Asked and 7 answered. 8 THE WITNESS: Again, these are volume 9 -averaged tests. You're not looking at the changes 10 at the surface. My testimony has been about these 11 changes that happen at the surface, oxidation. The 12 degradation at the surface is confirmed in this 13 study. This is a volume-averaged mechanical 14 property, and I don't know how to interpret it 15 because it's volume averaged, and they're not 16 looking specifically at what's happening at the 17 surface. That's -- that's the same way I would 18 explain the molecular weight. 19 BY MR. HUTCHINSON: 20 Q. And, Doctor, do you know how to 21 interpret the finding of a decrease of 70 percent of 22 Young's modulus at year seven? 23 MR. BOWMAN: Object to form. 24 THE WITNESS: I'll answer that the way</p> |

Scott Guelcher

| | |
|--|---|
| <p style="text-align: right;">Page 186</p> <p>1 I just answered. It's like molecular weight. It's 2 a -- it's a bulk property measurement, volume 3 averaged across the fiber, and it doesn't tell you 4 about what's happening on the surface. It doesn't 5 tell you whether the surface is embrittled. All 6 it's telling you is about the bulk properties of 7 the fiber. It's the same as the molecular weight. 8 I think limited information can be gained from 9 this. 10 BY MR. HUTCHINSON: 11 Q. Doctor, how -- how can a PROLENE fiber 12 be embrittled if its elongation increases 111 13 percent? 14 A. PROLENE fibers were embrittled in those 15 human explants, and they scraped it off. It was 16 embrittled, oxidized polypropylene. It was in the 17 reports that it was embrittled, oxidized material 18 on the surface. And doing these volume-averaged 19 bulk tests is not going to tell you what's 20 happening at the surface. 21 Q. And, Doctor, does the data from the dog 22 study support your opinions about whether or not 23 PROLENE degrades? 24 A. It says in the report that they were</p> | <p style="text-align: right;">Page 188</p> <p>1 volume-averaged data that don't look at what's 2 happening at the surface. 3 BY MR. HUTCHINSON: 4 Q. Do they support your opinions, Doctor? 5 A. I don't think they inform my opinions 6 because it's a volume-averaged property. It 7 doesn't look at what's happening at the surface. 8 Q. You don't -- 9 MR. HUTCHINSON: Move to strike as 10 nonresponsive. 11 BY MR. HUTCHINSON: 12 Q. You don't think they inform your 13 opinions. My question, Doctor, is do the -- do the 14 data summary support -- not inform -- support your 15 opinions that degradation occurs in vivo with 16 PROLENE? Does this data support -- does this data 17 summary support your opinions? 18 A. Again, it doesn't -- I -- I don't know 19 what to do with these data. These are 20 volume-averaged properties. It doesn't tell you 21 what's happening at the surface. 22 Q. I'm not asking you what -- to do 23 anything with them. I'm asking you whether or not 24 this data summary supports your opinions that</p> |
| <p style="text-align: right;">Page 187</p> <p>1 going through -- I believe it says -- 2 Q. The data summary. I'm talking about 3 the data summary, Doctor. Stick with me. On page 4 193, the bottom -- 5 A. Well, you have to be a little more 6 specific. The mechanical property summary. 7 Q. Excuse me. Excuse me. 8 A. Yeah. 9 Q. Do the mechanical properties, shown on 10 page 183 of the seven-year dog study, support your 11 opinions that PROLENE degrades in vivo? 12 A. I -- I don't think they're relevant to 13 my opinions because they -- this is a 14 volume-averaged quantity, just like the molecular 15 weight. It's averaged over the entire volume of 16 the suture. So it doesn't tell you what's 17 happening at the surface, where the degradation is 18 occurring. 19 Q. Does the data summary support your 20 opinions about degradation in vivo, Doctor? 21 MR. BOWMAN: Object to form. Asked and 22 answered. 23 THE WITNESS: I don't think it can 24 inform my opinions because these are</p> | <p style="text-align: right;">Page 189</p> <p>1 PROLENE degrades in vivo? 2 MR. BOWMAN: Object to form. 3 THE WITNESS: It's -- 4 MR. BOWMAN: Asked and answered. 5 THE WITNESS: It's difficult to form an 6 opinion about it because they're not measuring the 7 right thing. They're measuring a volume-averaged 8 property, not what's happening at the surface. So 9 it's difficult to form an opinion. 10 MR. HUTCHINSON: Move to strike as 11 nonresponsive. 12 BY MR. HUTCHINSON: 13 Q. Doctor, does the data summary support 14 your opinions? 15 MR. BOWMAN: I'm instructing you not to 16 answer. 17 THE WITNESS: I'm not answering. I 18 don't -- I don't want to go back and forth anymore. 19 I believe I've answered it. 20 BY MR. HUTCHINSON: 21 Q. Doctor, I forgot to ask you one 22 question when we were talking about the nine 23 different products. Can you tell the jury what the 24 difference is between TVT EXACT and TVT and any</p> |

Scott Guelcher

| | |
|--|--|
| <p style="text-align: right;">Page 190</p> <p>1 other -- and in any of the other TVT products?</p> <p>2 MR. BOWMAN: Object to form.</p> <p>3 THE WITNESS: I don't remember the</p> <p>4 specific differences. There's differences in how</p> <p>5 the mesh can be cut, machine cut, laser cut.</p> <p>6 They're all made from the same mesh, which is what</p> <p>7 I was looking at in my report. They're all made</p> <p>8 from the same PROLENE, from the same -- from the</p> <p>9 same mesh, as I said earlier.</p> <p>10 BY MR. HUTCHINSON:</p> <p>11 Q. Doctor, is TVT ABBREVO laser cut or</p> <p>12 mechanically cut?</p> <p>13 MR. BOWMAN: Object to form.</p> <p>14 THE WITNESS: I can't remember. I</p> <p>15 believe it's laser cut. TVT's mechanically cut. I</p> <p>16 don't remember the details of it.</p> <p>17 BY MR. HUTCHINSON:</p> <p>18 Q. Doctor, do you know -- can you tell the</p> <p>19 jury whether or not TVT-O is mechanically cut or</p> <p>20 laser cut?</p> <p>21 A. I believe TVT-O is mechanically cut.</p> <p>22 Q. Doctor, are you aware of whether or not</p> <p>23 TVT-O is available in any type of other -- strike</p> <p>24 that.</p> | <p style="text-align: right;">Page 192</p> <p>1 A. PROSIMA is not a sling. It's a --</p> <p>2 Q. I'm not asking about the product. I'm</p> <p>3 asking about can you tell us how the mesh in</p> <p>4 PROSIMA is cut?</p> <p>5 A. I -- I don't remember. I wasn't</p> <p>6 stating opinions about the cutting of the mesh in</p> <p>7 my report.</p> <p>8 Q. Doctor, does the cutting of the mesh</p> <p>9 influence your opinions whatsoever regarding</p> <p>10 oxidizing PROLENE?</p> <p>11 MR. BOWMAN: Object to form.</p> <p>12 THE WITNESS: Well, the cutting of the</p> <p>13 mesh could affect the oxidation reaction.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. Is that stated in your report marked as</p> <p>16 Exhibit 2, Doctor?</p> <p>17 A. I don't believe that's in my report.</p> <p>18 Q. Okay. Doctor, can you tell us how the</p> <p>19 mesh in GYNEMESH PS is cut?</p> <p>20 MR. BOWMAN: Object to form.</p> <p>21 THE WITNESS: I don't remember how that</p> <p>22 mesh is cut.</p> <p>23 BY MR. HUTCHINSON:</p> <p>24 Q. Can you tell us how the mesh in PROLIFT</p> |
| <p style="text-align: right;">Page 191</p> <p>1 Are you aware if TVT -- if TVT-O is</p> <p>2 available in laser cut mesh?</p> <p>3 A. I can't remember. Some of these</p> <p>4 products are offered as machine cut and laser cut.</p> <p>5 It's not always specified which the cut is.</p> <p>6 Sometimes it's difficult to figure out. But --</p> <p>7 Q. Is it your testimony, Doctor, it's not</p> <p>8 always specified in the product literature how the</p> <p>9 mesh is cut?</p> <p>10 A. I don't remember how the -- how the --</p> <p>11 the specifics of how the mesh is cut. Again, I was</p> <p>12 focusing on the specific PROLENE used in the mesh</p> <p>13 and its implantation in the body.</p> <p>14 Q. Doctor, can you tell us how the mesh in</p> <p>15 the TVT SECUR is cut?</p> <p>16 A. I believe that's a machine cut.</p> <p>17 Q. And can you tell us, Doctor, how the</p> <p>18 mesh in TVT EXACT is cut?</p> <p>19 MR. BOWMAN: Object to form.</p> <p>20 THE WITNESS: I don't remember about</p> <p>21 TVT EXACT.</p> <p>22 BY MR. HUTCHINSON:</p> <p>23 Q. Can you tell us how the mesh in PROSIMA</p> <p>24 is cut?</p> | <p style="text-align: right;">Page 193</p> <p>1 is cut?</p> <p>2 A. I don't remember how that mesh is cut.</p> <p>3 Q. Can you tell us how the mesh in</p> <p>4 PROLIFT+M is cut?</p> <p>5 A. I don't remember how that mesh is cut</p> <p>6 either.</p> <p>7 Q. Doctor, do you have any opinions</p> <p>8 whatsoever regarding how the mesh is cut as it</p> <p>9 relates to its reaction with tissue?</p> <p>10 MR. BOWMAN: Object to form.</p> <p>11 THE WITNESS: I mean, I thought I</p> <p>12 answered it. Those opinions are not in this</p> <p>13 report.</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. And you're not offering any opinions</p> <p>16 about that in relation to the nine different</p> <p>17 products at issue here today, correct?</p> <p>18 A. I'm not offering any opinions about</p> <p>19 that.</p> <p>20 Q. Doctor, have --</p> <p>21 MR. BOWMAN: Counsel, I actually have</p> <p>22 that the three hours are up.</p> <p>23 MR. HUTCHINSON: Okay.</p> <p>24 BY MR. HUTCHINSON:</p> |

Scott Guelcher

| | |
|---|--|
| <p style="text-align: right;">Page 194</p> <p>1 Q. Doctor, do you intend to offer any 2 opinions in this case that we've not already 3 discussed? 4 A. No. 5 Q. Do you plan on supplementing your 6 opinions? 7 A. I don't know. 8 Q. Okay. Have you understood all of my 9 questions so far? 10 A. Mostly. 11 Q. Is there a question that's lingering in 12 your mind that you don't understand that I need to 13 reask? 14 MR. BOWMAN: I did instruct him not to 15 answer at least two questions. 16 THE WITNESS: No. 17 BY MR. HUTCHINSON: 18 Q. Doctor, is there anything about the 19 testimony you've given today that you would like to 20 change? 21 A. No. 22 Q. Do you feel good about how you did 23 today as an expert witness? 24 MR. BOWMAN: Object to form.</p> | <p style="text-align: right;">Page 196</p> <p>1 CERTIFICATE 2 STATE OF TENNESSEE) 3 COUNTY OF DAVIDSON) 4 I, Lise S. Matthews, RMR, CRR, CCP, LCR 5 353, Licensed Court Reporter and Notary Public, in 6 and for the State of Tennessee, do hereby certify 7 that the above deposition was reported by me, and 8 the transcript is a true and accurate record to the 9 best of my knowledge, skills, and ability. 10 I further certify that I am not related 11 to nor an employee of counsel or any of the parties 12 to the action, nor am I in any way financially 13 interested in the outcome of this case. 14 I further certify that I am duly 15 licensed by the Tennessee Board of Court Reporting 16 as a Licensed Court Reporter as evidenced by the 17 LCR number and expiration date following my name 18 below. I further certify that this transcript is 19 the work product of this court reporting agency and 20 any unauthorized reproduction and/or transfer of it 21 will be in violation of Tennessee Code Annotated 22 39-14-104, Theft of Services. 23 IN WITNESS WHEREOF, I have hereunto set 24 my hand and affixed my notarial seal this _____ day of _____, 2016.</p> <p>16 Lise S. Matthews, RMR, CRR, CRC 17 LCR 353 Expiration Date 6/30/2016 18 Notary Public Commission Expires 19 March 6, 2018 20 21 22 23 24</p> |
| <p style="text-align: right;">Page 195</p> <p>1 THE WITNESS: I don't know. Our three 2 hours is up. I think we're done. 3 MR. HUTCHINSON: Thank you. 4 Counsel, before we go -- we go off the 5 record, just to make a housekeeping note, counsel 6 has given me a flash drive that contains what? 7 MR. BOWMAN: Reliance materials, pretty 8 much everything that was reviewed or referenced in 9 the report. 10 MR. HUTCHINSON: Okay. 11 (Proceedings concluded at 12:17 p.m.) 12 13 14 15 16 17 18 19 20 21 22 23 24</p> | |